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Policy for Device Software Functions and Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

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Preface

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Policy for Device Software Functions and Mobile Medical Applications

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) recognizes the extensive variety of actual and potential functions of software applications (apps) and mobile apps, the rapid pace of innovation, and their potential benefits and risks to public health. The FDA is issuing this guidance document to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms (mobile applications or “mobile apps”) or on general-purpose computing platforms. Given the rapid expansion and broad applicability of software functions deployed on mobile or other general-purpose computing platforms, the FDA is issuing this guidance document to clarify the subset of software functions to which the FDA intends to apply its authority.

FDA refers to software functions that are device functions as “device software functions.” Device software functions may include “Software as a Medical Device (SaMD)” and “Software in a Medical Device (SiMD).”1,2 Software functions that meet the definition of a device may be deployed on mobile platforms, other general-purpose computing platforms, or in the function or control of a hardware device. If a software function that meets the definition of a device is deployed on a mobile platform, it may be referred to as a “mobile medical app.” The policies described in this guidance are independent of the platform on which they might run, are function-specific, and apply across platforms. Therefore, the policies described using terms such as “mobile medical apps,” “mobile medical app manufacturers,” “device software functions,” and “device software function manufacturers”

1 See FDA website on “Software as a Medical Device (SaMD),” available at https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd.
are not specific to whether the function is deployed on a mobile platform or other general purpose-computing platform.

Many software functions are not medical devices (meaning such software functions do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them as devices. Some software functions may meet the definition of a medical device, but because they pose a lower risk to the public, FDA intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the FD&C Act).

Consistent with the FDA’s existing oversight approach that considers functionality of the software rather than platform, the FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient’s safety if the device were to not function as intended.

FDA is issuing this guidance to provide clarity and predictability for software manufacturers. This document has been updated to be consistent with section 3060(a) of the 21st Century Cures Act, which amended section 520 of the FD&C Act, removing certain software functions from the definition of device in section 201(h) of the FD&C Act, and the guidance document entitled “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” originally issued on February 9, 2015. ³ Examples of mobile apps and software on the FDA web site⁴ (that were added after September 25, 2013) were incorporated into the appropriate appendices of this document for consistency.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database. ⁵ For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices⁶ and “Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research.”⁷

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidelines describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

II. Background

As mobile platforms become more user friendly, computationally powerful, and readily available, innovators have begun to develop mobile apps of increasing complexity to leverage the portability mobile platforms can offer. Some of these new software functions are specifically targeted to assisting individuals in their own health and wellness management. Other software functions are targeted to health care providers as tools to improve and facilitate the delivery of patient care.

In 1989, FDA prepared a general policy statement on how it planned to determine whether a computer-based product and/or software-based product is a device, and, if so, how the FDA intended to regulate it. The document, “FDA Policy for the Regulation of Computer Products,” became known as the “Draft Software Policy.” After 1989, however, the use of computer and software products as medical devices grew exponentially and the types of products diversified and grew more complex (and that trend has continued). As a result, the FDA determined that the draft policy did not adequately address all of the issues related to the regulation of all medical devices containing software. Therefore, in 2005, the Draft Software Policy was withdrawn.\(^8\)

Although the FDA has not issued an overarching software policy, the Agency has formally classified certain types of software applications that meet the definition of a device and, through classification, identified specific regulatory requirements that apply to these devices and their manufacturers. These software devices include products that feature one or more software components, parts, or accessories, as well as devices that are composed solely of software.

The FDA has previously clarified that when a software application is used to analyze medical device data, it has traditionally been regulated as an accessory to a medical device\(^9\) or as medical device software. In 2014, the International Medical Device Regulators Forum established globally harmonized vocabulary for such software applications and defined the term “Software as a Medical Device (SaMD).\(^{10}\)

As is the case with traditional medical devices, certain software functions that are device functions (referred to in this document as ‘device software functions’) can pose potential risks to public health. Moreover, certain device software functions may pose risks that are unique to the characteristics of the platform on which the software function is run. For example, the interpretation of radiological images on a mobile device could be adversely

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\(^8\) Annual Comprehensive List of Guidance Documents at the Food and Drug Administration (70 FR 824 at 890) (January 5, 2005).


\(^{10}\) See the International Medical Device Regulators Forum final document, “Software as a Medical Device (SaMD): Key Definitions,” available at http://www.imdrf.org/docs/imdrf/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf.
affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform. FDA intends to take these risks into account in assessing the appropriate regulatory oversight for these products.

This guidance clarifies and outlines the FDA’s current thinking. The Agency will continue to evaluate the potential impact these technologies might have on improving health care, reducing potential medical mistakes, and protecting patients.

III. Definitions

A. Mobile Platform

For purposes of this guidance, “mobile platforms” are defined as commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other portable computers.

B. Mobile Application (Mobile App)

For purposes of this guidance, a mobile application or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

C. Mobile Medical Application (Mobile Medical App)

For purposes of this guidance, a “mobile medical app” is a mobile app that incorporates device software functionality that meets the definition of device in section 201(h) of the FD&C Act\(^\text{11}\); and either is intended:

- to be used as an accessory to a regulated medical device; or

\(^{11}\) Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as “…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory”, that is “…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man …” or “…intended to affect the structure or any function of the body of man or other animals…” and “does not include software functions excluded pursuant to section 520(o) of the FD&C Act.” Thus, software applications that run on a desktop computer, laptop computer, remotely on a website or “cloud,” or on a handheld computer may be subject to device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The level of regulatory control necessary to assure safety and effectiveness varies based upon the risk the device presents to public health. (See Appendix D for examples).
to transform a mobile platform into a regulated medical device.

The intended use of a mobile app determines whether it meets the definition of a “device.” As stated in 21 CFR 801.4, intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representatives. When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device under section 201(h) of the FD&C Act if it is not a software function excluded from the device definition by section 520(o) of the FD&C Act.

One example is a mobile app that makes a light emitting diode (LED) operate. If the manufacturer intends the system to illuminate objects generally (i.e., without a specific medical device intended use), the mobile app would not be considered a medical device. If, however, through marketing, labeling, and the circumstances surrounding the distribution, the mobile app is promoted by the manufacturer for use as a light source for doctors to examine patients, then the intended use of the light source would be similar to a conventional device such as an ophthalmoscope.

In general, if a software function is intended for use in performing a medical device function (i.e. for diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease) it is a medical device, regardless of the platform on which it is run. For example, mobile apps intended to run on smart phones to analyze and interpret EKG waveforms to detect heart function irregularities would be considered similar to software running on a desktop computer that serves the same function, which is regulated under 21 CFR 870.2340 (“Electrocardiograph”). FDA’s oversight approach to software functions is focused on their functionality, just as we focus on the functionality of conventional devices. Our oversight is not determined by the platform. Under this guidance, FDA would not regulate the sale or general/conventional consumer use of smartphones or tablets. FDA’s oversight applies to software functions performing medical device functions, such as when a mobile medical app or software application transforms a mobile platform or a general purpose computing platform into a medical device. However, as previously noted, we intend

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12 “The words ‘intended uses’ or words of similar import ... refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.” 21 CFR 801.4.

13 “The term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” Section 201(m) of the FD&C Act, 21 U.S.C. 321(m).
to apply this oversight authority only to those software applications whose functionality could pose a risk to a patient’s safety if the software applications were to not function as intended.

D. Regulated Medical Device

For purposes of this guidance, a “regulated medical device” is defined as a product that meets the definition of device in section 201(h) of the FD&C Act and that has been cleared or approved by the FDA review of a premarket submission or otherwise classified by the FDA.

This definition can include novel devices, whether or not on a mobile platform, that the FDA will clear or approve by the review of a premarket submission or otherwise classify. Examples of regulated medical devices are identified in Appendix D.

E. Mobile Medical App Manufacturer

For purposes of this guidance, a “mobile medical app manufacturer” is any person or entity that manufactures mobile medical apps in accordance with the definitions of manufacturer in 21 CFR Parts 803, 806, 807, and 820. A mobile medical app manufacturer may include anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components. This term does not include persons who exclusively distribute mobile medical apps without engaging in manufacturing functions; examples of such distributors may include owners and operators of “Google Play,” “iTunes App Store,” and “BlackBerry App World.” Examples of mobile medical app manufacturers include any person or entity that:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components. This could include a person or entity that creates a mobile medical app by COTS software components and markets the product to perform as a mobile medical app;

- Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution. For example, when a “developer” (i.e., an entity that provides engineering, design, and development services) creates a mobile

14 Regulatory definitions of the term “manufacturer” or “manufacture” appear in 21 CFR Parts 803, 806, 807, and 820. For example – under FDA’s 21 CFR 807.3(d) – establishment registration and device listing for manufacturers and initial importers of devices – “Manufacture, preparation, propagation, compounding, assembly, or processing of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities: (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer; (2) Initial importation of devices manufactured in foreign establishments; or (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications.”
medical app from the specifications that were initiated by the “author,” the “author” who initiated and developed specifications for the mobile medical app is considered a “manufacturer” of the mobile medical app under 21 CFR 803.3. For purposes of this guidance, manufacturers of a mobile medical app would include persons or entities who are the creators of the original idea (initial specifications) for a mobile medical app, unless another entity assumes all responsibility for manufacturing and distributing the mobile medical app, in which case that other entity would be the “manufacturer.”15 Software “developers” of a mobile medical app that are only responsible for performing design and development activities to transform the author’s specifications into a mobile medical app would not constitute manufacturers, and instead the author would be considered the manufacturer;

- Creates a mobile medical app and hardware attachments for a mobile platform that are intended to be used as a medical device by any combination of the mobile medical app, hardware attachments, and the mobile platform;

- Creates a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service,16 or other similar means.

In contrast, the following are examples of persons or entities that are NOT considered to be mobile medical app manufacturers (i.e., persons not within the definition of manufacturer in 21 CFR Parts 803, 806, 807, and 820). Because they are not manufacturers, none of the persons or entities in these examples would have to register their establishments, list their products with the FDA,17 or submit a premarket application:

- Manufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims – e.g., labeling claims or advertising material) the platform to be used for medical device functions. When mobile medical apps are run on a mobile platform, the mobile platform is treated as a component of the mobile medical app’s intended use.18 Therefore the mobile platform manufacturer is exempt from the Quality System regulation and registration and listing requirements.19 For example, if it is possible to run mobile medical apps on BrandNamePhone but BrandNamePhone is not marketed by BrandNameCompany as intended for use as a medical device, then BrandNameCompany would not be considered a mobile medical app manufacturer or a medical device manufacturer. Also, in this example, the BrandName Phone sold to consumers would not be regulated by FDA as a medical device. FDA does not consider entities that

15 See 21 CFR 803.3 (definition of manufacturer) and 21 CFR 807.20(a)(2).
16 By this we mean to include any “server software application” that provides a service to a client software application on a mobile platform.
18 See 21 CFR 820.3(c), which defines a component as “any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.”
19 See 21 CFR 807.65(a) and 21 CFR 820.1(a).
exclusively distribute mobile medical apps, such as the owners and operators of the “iTunes App Store” or the “Android Market,” to be medical device manufacturers. FDA also does not consider mobile platform manufacturers to be medical device manufacturer just because their mobile platform could be used to run a mobile medical app regulated by FDA.

- Third parties who solely provide market access to mobile medical apps (i.e. solely distribute mobile apps), but do not engage in any manufacturing functions as defined in 21 CFR Parts 803, 806, 807, and 820. Examples of such third parties may include owners and operators that are only engaged in providing an online market place that allow mobile medical app manufacturers to commercially distribute their mobile medical apps. Specific examples of such online market places include “Google Play,” “iTunes Store,” and “BlackBerry App World”;

- Providers of tools, services, or infrastructure used in the development, distribution, or use of a mobile medical app. Examples include providers of internet connectivity (i.e., internet service), providers of general-purpose computer or information technology, providers that host the web service for content or software application. Other examples of providers of tools, services, or infrastructure include customer support services, data center hosting services, cloud hosting services, application hosting services, wireless carriers, or providers of software development kits. However, a creator of a mobile medical app or a software system that provides users access to the medical device function through a website subscription, software as a service,\(^{20}\) or other similar means is considered a mobile medical app manufacturer;

- Licensed practitioners, including physicians, dentists, and optometrists, who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice and do not label or promote their mobile medical apps to be generally used by other licensed practitioners or other individuals.\(^ {21,22}\) For example, if Dr. XYZ, a licensed practitioner, creates a mobile medical app called the “XYZ-recorder” that enables attaching an ECG electrode to a smartphone, and provides the “XYZ-recorder” to his/her patient to use it to record the patient’s electrocardiographic readings for 24 hours, Dr. XYZ is not considered a mobile medical app manufacturer. If Dr. XYZ is in a group practice (including a telehealth network) and permits other physicians in the practice to provide the XYZ-recorder to their patients, Dr. XYZ is not considered a mobile medical apps manufacturer. However, if Dr. XYZ, the licensed practitioner, distributes the “XYZ-recorder” and, through labeling or promotion intends to make it generally available to or to be

\(^{20}\) As identified in footnote 15, we mean to include any “server software application” that provides a service to a client software application on a mobile platform.

\(^{21}\) Section 510(g)(2) of the FD&C Act: “Practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice.”

\(^{22}\) See 21 CFR 807.65(d).
generally used by other physicians (or other specially qualified persons), Dr. XYZ would be considered a mobile medical app manufacturer;

- Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution. We note that while persons conducting research using mobile medical apps involving human subjects are exempt from registration and listing, they may instead be subject to investigational device exemption regulations.23,24

IV. Scope
This guidance explains the FDA’s intentions to focus its oversight on a subset of software functions. Mobile medical apps, as defined in Section III, include only those mobile apps that meet the definition of a device and either are intended:

- to be used as an accessory to a regulated medical device; or
- to transform a mobile platform into a regulated medical device.

Appendix A provides examples of software functions, some of which are mobile apps, that FDA does NOT consider to meet the definition of a device and, therefore, are NOT device software functions or mobile medical apps for the purposes of this guidance.

Section V.B and Appendix B provide examples of software functions, some of which are mobile apps, that MAY meet the definition of a device but for which the FDA intends to exercise enforcement discretion because they pose a low risk to patients.25

This guidance does not address the approach for software that performs patient-specific analysis to aid or support clinical decision-making.

FDA’s policies regarding accessories to medical devices are not unique to device software functions and go beyond the scope of this guidance. Specifically this guidance does not address FDA’s general approach for accessories to medical devices.

If you are developing a software function that meets the definition of a device (such as a mobile medical app) with an entirely new intended use, we encourage you to contact FDA to discuss what regulatory requirements may apply.

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23 See 21 CFR 807.65(f).
24 See 21 CFR 812.1.
25 This indicates that for certain device software functions, such as those in Appendix B, the FDA intends not to pursue enforcement action for violations of the FD&C Act and applicable regulations by a manufacturer of a software function that meets the definition of a device in section 201(h) of the FD&C Act as specified in this guidance. This does not constitute a change in the requirements of the FD&C Act or any applicable regulation.
V. Regulatory Approach for Device Software Functions

As described in this guidance, FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient’s safety if the device were to not function as intended. This approach to overseeing device software functions is consistent with our existing approach to overseeing medical device functionality of a product and the risks it poses to patients regardless of the shape, size, or the platform. The FDA believes that this subset of device software functions poses the same or similar potential risks to the public health as currently regulated devices if they fail to function as intended.

The FDA strongly recommends that manufacturers of all software and mobile apps that may meet the definition of a device follow the Quality System regulation (that includes good manufacturing practices) in the design and development of their device software functions, and initiate prompt corrections to their devices, when appropriate, to prevent patient and user harm.

For device software functions, manufacturers must meet the requirements associated with the applicable device classification. If the device, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification. A device software function, like other devices, may be classified as class I (general controls), class II (special controls in addition to general controls), or class III (premarket approval).

A. Device software functions: Subset of software functions that are the focus of FDA’s regulatory oversight

Software functions may take a number of forms, but it is important to note that the FDA intends to apply its regulatory oversight to only the subset of software functions identified below and in Appendix C. These software functions can transform a general-purpose computing platform or mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods. Regardless of the mechanism behind the transformation, FDA considers such software to be device software functions.

The following are software functions that FDA considers to be device software functions subject to regulatory oversight:

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26 See 21 CFR Part 820.
27 See footnotes 8 and 10.
1. **Software functions that are an extension of one or more medical devices by connecting**\(^{28}\) to such device(s) for purposes of controlling\(^{29}\) the device(s) or analyzing medical device data.

   - *Examples of software functions that control medical devices include:* software that provides the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform.

   Device software functions of these types are considered accessories to the connected device and are required to comply with the controls applicable to that connected device. The FDA considers such device software functions to extend the intended use and functionality of the connected medical device. As a result, the device software function would be required to comply with the regulations applicable to the connected medical device in order to address any associated risks.

2. **Software functions (typically, mobile apps) that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. Software functions that use attachments, display screens, sensors or other such similar components to transform a mobile platform into a regulated medical device are required to comply with the device classification associated with the transformed platform.**

   - *Examples of these types of software functions include:* a software function that uses a mobile platform for medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; or attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; a software function that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; a software function that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function is considered to transform the mobile platform into an electronic stethoscope; manufacturers of such a mobile app are required to follow the requirements of 21 CFR 870.1875(b) (Electronic Stethoscope); and similarly a software function that displays radiological images for diagnosis transforms the mobile platform into a class II Picture Archiving and Communications System (PACS) under 21 CFR 892.2050.

The FDA has cleared several mobile medical apps with attachments to a mobile platform. Specifically, patient monitoring mobile apps that monitor a

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\(^{28}\) To meet this criterion, the device software functions or mobile medical apps need not be physically connected to the regulated medical device (i.e. the connection can be wired or wireless).

\(^{29}\) Controlling the intended use, function, modes, or energy source of the connected medical device.
patient for heart rate variability from a signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor are classified as cardiac monitoring software under 21 CFR 870.2300 (Cardiac monitor). Other mobile medical apps that use a hardware attachment or interface to a monitoring system that have been cleared include an automatic electronic blood pressure monitor under 21 CFR 870.1130 and a perinatal monitoring system under 21 CFR 884.2740.

3. **Software functions that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations.** These types of functions are similar to or perform the same function as those types of software devices that have been previously cleared or approved.

   o *Examples of software functions that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device include:* software functions that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software (CAD) image processing software\(^{30}\); and radiation therapy treatment planning software\(^{31}\). We believe that these types of software present the same level of risk to patients regardless of the platform on which they run.

The FDA encourages manufacturers of such device software functions that perform patient-specific analysis to contact FDA to discuss what, if any, regulatory requirements may apply. For additional examples see Appendix C.

**B. Software functions for which FDA intends to exercise enforcement discretion (meaning that FDA does not intend to enforce requirements under the FD&C Act)**

FDA intends to exercise enforcement discretion for software functions that:

1. Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions; or
2. Automate simple tasks for health care providers.

Some software functions in the above categories and listed below may be considered device software functions, and others might not. For these examples listed below that are devices, FDA intends to exercise enforcement discretion because they pose a low risk to patients.

\(^{30}\) 21 CFR 892.2050.

\(^{31}\) 21 CFR 892.2050.
The following examples represent software functions for which the FDA intends to exercise enforcement discretion:

3. **Software functions that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment** – These are software functions that supplement\(^\text{32}\) professional clinical care by facilitating behavioral change or coaching patients with specific diseases or identifiable health conditions in their daily environment. Examples include:

   - Software functions that coach patients with conditions such as cardiovascular disease, hypertension, diabetes, or obesity, and promote strategies for maintaining a healthy weight, getting optimal nutrition, exercising and staying fit, managing salt intake, or adhering to pre-determined medication dosing schedules\(^\text{33}\) by simple prompting.

4. **Software functions that provide easy access to information related to patients’ health conditions or treatments (beyond providing an electronic “copy” of a medical reference)** – This includes software that provides contextually-relevant information to users by matching patient-specific information (e.g., diagnosis, treatments, allergies, signs, or symptoms) to reference information routinely used in clinical practice\(^\text{34}\) (e.g., practice guidelines) to facilitate a user’s assessment of a specific patient. Examples include:

   - Software functions that use a patient’s diagnosis to provide a clinician with best practice treatment guidelines for common illnesses or conditions such as influenza; or
   - Software functions that are drug-drug interaction or drug-allergy look-up tools.

5. **Software functions that are specifically marketed to help patients communicate with healthcare providers by supplementing or augmenting the data or information by capturing an image for patients to convey to their healthcare providers about potential medical conditions** – These products either pose little or no risk, or are the sole responsibility of the health care providers who have experience with them in medical applications. Examples include:

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\(^{32}\) By this we mean that the app can be safely used by a patient without active oversight by a medical professional and, when used for serious conditions necessitating professional medical care, use of the app is not intended to replace or discourage seeking treatment from a health care provider.

\(^{33}\) We consider these device software functions to be “medication reminders – Product code NXQ” currently defined as “A medication reminder is a device intended for medical purposes to provide alerts to patients or health care providers for pre-determined medication dosing schedules. The device may incorporate wireless communication.” The FDA intends to not enforce applicable regulatory requirements for this specific product code (NXQ) identified under 21 CFR 890.5050 – Daily activity assist device.

\(^{34}\) The type of information provided is from authoritative medical sources, as recognized by the field or discipline that is the subject of the software.
Contains Nonbinding Recommendations

- Apps specifically intended for medical uses that utilize the mobile device’s built-in camera or a connected camera for purposes of documenting or transmitting pictures (e.g., photos of a patient’s skin lesions or wounds) to supplement or augment what would otherwise be a verbal description in a consultation between health care providers or between health care providers and patients/caregivers.

6. **Software functions that perform simple calculations routinely used in clinical practice** – These are software functions that are intended to provide a convenient way for clinicians to perform various simple medical calculations taught in medical schools\(^\text{35}\) and are routinely used in clinical practice. This software is generally tailored for clinical use, but retains functionality that is similar to simple general-purpose tools such as paper charts, spread sheets, timers, or generic mathematical calculators. Examples of such general-purpose tools include medical calculators for:

- Body Mass Index (BMI);
- Total Body Water / Urea Volume of Distribution;
- Mean arterial pressure;
- Glasgow Coma Scale score;
- APGAR score;
- NIH Stroke Scale; or
- Delivery date estimator.

See Appendix B for additional examples for the above categories.

**VI. Regulatory Requirements**

This guidance, including Appendix C and existing medical device regulatory classifications in Appendix D, is intended to assist manufacturers in determining if the software functionality meets the definition of a device and FDA’s expectations for that product. Additional information can be found in “Device Advice: Classify Your Medical Device.”\(^\text{36}\) This section describes in greater detail the regulatory requirements applicable to device software functions under this guidance (as described in Section V).

Manufacturers of device software functions are subject to the requirements described in the applicable device classification regulation below. Depending on the classification and the associated regulation for the device software function, manufacturers are required to follow associated controls established by the regulation.

In general, the associated controls for each class of device are outlined below.

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\(^{35}\) The types of information in these calculators are available in medical sources, which includes medical textbooks used in the curriculum of accredited medical schools.

Contains Nonbinding Recommendations

Class I devices: General Controls, including:

- Establishment registration, and Medical Device listing (21 CFR Part 807);
- Quality System (QS) regulation (21 CFR Part 820);
- Labeling Requirements (21 CFR Part 801);
- Medical Device Reporting (21 CFR Part 803);
- Premarket Notification (21 CFR Part 807);
- Reporting Corrections and Removals (21 CFR Part 806); and
- Investigational Device Exemption (IDE) requirements for clinical studies of investigational devices (21 CFR Part 812).

Class II devices: General Controls (as described for Class I), Special Controls, and (for most Class II devices) Premarket Notification.

Class III devices: General Controls (as described for Class I), and Premarket Approval (21 CFR Part 814).

Appendix E provides a brief summary of the above requirements. Additional information is available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance, under “Overview of Medical Device Regulation” and “How to Study and Market Your Device.” If you need further assistance, you may contact the Division of Industry and Consumer Education (DICE): Email: DICE@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.

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38 Available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.
Appendix A  Examples of Software Functions that are NOT Medical Devices

This Appendix provides a representative list of software functionalities to illustrate the types of software that could be used in a health care environment, in clinical care, or patient management, but are not considered medical devices. Because these software functions are not considered medical devices, FDA does not regulate them. The FDA understands that there may be other unique and innovative software functions that may not be covered in this list that may also constitute health care related software. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying when a software function is not considered to be a medical device.

Specific examples of software functions that FDA does not consider to be devices and with no regulatory requirements under the current laws administered by FDA include:

1. **Software functions that are intended to provide access to electronic “copies” (e.g., e-books, audio books) of medical textbooks or other reference materials with generic text search capabilities** – These are not devices because the software is intended to be used as reference material and is not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by facilitating a health professional’s assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples of these types of software functions include:
   - Medical dictionaries;
   - Electronic copies of medical textbooks or literature articles such as the Physician’s Desk Reference or Diagnostic and Statistical Manual of Mental Disorders (DSM);
   - Library of clinical descriptions for diseases and conditions;
   - Encyclopedia of first-aid or emergency care information;
   - Medical abbreviations and definitions;
   - Translations of medical terms across multiple languages.

2. **Software functions that are intended for health care providers to use as educational tools for medical training or to reinforce training previously received** – These may have more functionality than providing an electronic copy of text (e.g., videos, interactive diagrams), but are not devices because they are intended generally for user education and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by facilitating a health professional’s assessment of a specific patient, replacing the judgment of clinical personnel, or performing any clinical assessment. Examples of these types of software functions include:
   - Medical flash cards with medical images, pictures, graphs, etc.;
   - Question/Answer quiz apps;
o Interactive anatomy diagrams or videos;
o Surgical training videos;
o Medical board certification or recertification preparation apps;
o Games that simulate various cardiac arrest scenarios to train health professionals in advanced CPR skills.

3. **Software functions that are intended for general patient education and facilitate patient access to commonly used reference information** – This software can be patient-specific (i.e., filters information to patient-specific characteristics), but is intended for increased patient awareness, education, and empowerment, and ultimately supports patient-centered health care. These functions are not devices because they are intended generally for patient education, and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease by aiding clinical decision-making (i.e., to facilitate a health professional’s assessment of a specific patient, replace the judgment of a health professional, or perform any clinical assessment). Examples include software functions that:

   o Provide a portal for health care providers to distribute educational information (e.g., interactive diagrams, useful links, and resources) to their patients regarding their disease, condition, treatment, or up-coming procedure;
o Help guide patients to ask appropriate questions to their physician relevant to their particular disease, condition, or concern;
o Provide information about gluten-free food products or restaurants;
o Help match patients with potentially appropriate clinical trials and facilitate communication between the patient and clinical trial investigators;
o Provide tutorials or training videos on how to administer first-aid or CPR;
o Allow users to input pill shape, color, or imprint and displays pictures and names of pills that match this description;
o Find the closest medical facilities and doctors to the user’s location;
o Provide lists of emergency hotlines and physician/nurse advice lines;
o Provide and compare costs of drugs and medical products at pharmacies in the user’s location.

4. **Software functions that automate general office operations in a health care setting** and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Examples include software functions that:

   o Determine billing codes like ICD-9 (international statistical classification of diseases);
o Enable insurance claims data collection and processing and other apps that are similarly administrative in nature;
o Analyze insurance claims for fraud or abuse;
o Perform medical business accounting functions or track and trend billable hours and procedures;
Contains Nonbinding Recommendations

- Generate reminders for scheduled medical appointments or blood donation appointments;
- Help patients track, review, and pay medical claims and bills online;
- Manage shifts for doctors;
- Manage or schedule hospital rooms or bed spaces;
- Provide wait times and electronic check-in for hospital emergency rooms and urgent care facilities;
- Allow health care providers or staff in health care settings to process payments (for example, using a HIPAA compliant app to process payments);
- Track or perform patient satisfaction survey after an encounter or a clinical visit.

5. **Software functions that are generic aids or general-purpose products** – This software is not considered a device because it is not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Examples include software functions that:

   - Use the mobile platform as a magnifying glass (but are not specifically intended for medical purposes\(^{39}\));
   - Use the mobile platform for recording audio, note-taking, replaying audio with amplification, or other similar functionalities;
   - Allow patients or health care providers to interact through email, web-based platforms, video, or other communication mechanisms (but are not specifically intended for medical purposes);
   - Provide maps and turn-by-turn directions to medical facilities;
   - Allow health care providers to communicate in a secure and protected method (for example using a HIPAA compliant app to send messages between health care providers in a hospital).

6. **Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness**, such as those that:

   - Provide tools to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness;
   - Provide dietary logs, calorie counters or make dietary suggestions;
   - Provide meal planners and recipes;
   - Track general daily activities or make exercise or posture suggestions;
   - Track a normal baby’s sleeping and feeding habits;
   - Actively monitor and trend exercise activity;

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\(^{39}\) Medical purpose magnifiers are regulated either under 21 CFR 886.5840 – Magnifying spectacles (“devices that consist of spectacle frames with convex lenses intended to be worn by a patient who has impaired vision to enlarge images”), or under 21 CFR 886.5540 – Low-vision magnifiers (“a device that consists of a magnifying lens intended for use by a patient who has impaired vision. The device may be held in the hand or attached to spectacles”).
Contains Nonbinding Recommendations

- Help healthy people track the quantity or quality of their normal sleep patterns;
- Provide and track scores from mind-challenging games or generic “brain age” tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.

7. **Software functions that enable individuals to interact with EHR software certified under the ONC Health IT Certification Program** – These are software functions that provide individuals with access to health record systems or enable them to gain electronic access to health information stored within an EHR system. Software functions that only allow individuals to view, transfer, or download EHR data are also included in this category. These software functions are generally meant to facilitate general patient health information management and health record-keeping activities.

8. Software functions that provide patients with simple tools to organize and track their health information;

9. Software functions that provide easy access to information related to patients’ health conditions or treatments;

10. **Software functions that provide patients with simple tools to organize and record their health information** – These are software functions that provide patients with tools to organize and record health information without providing recommendations to alter or change a previously prescribed treatment or therapy. Examples include:

    - Software functions that provide simple tools for patients with specific conditions or chronic disease (e.g., obesity, anorexia, arthritis, diabetes, heart disease) to record their events or measurements (e.g., blood pressure measurements, drug intake times, diet, daily routine, or emotional state) and share this information with their health care provider as part of a disease-management plan.

11. **Software functions that are specifically marketed to help patients document, show, or communicate to providers regarding potential medical conditions** – These products either pose little or no risk, or are the sole responsibility of the health care providers who have used them in medical applications. Examples include:

    - Software that serves as a videoconferencing portal specifically intended for medical use and to enhance communications between patients, health care providers, and caregivers.
12. Software functions that enable, during an encounter, a health care provider to access their patient’s personal health record (health information) that is hosted on a web-based or other platform;

13. Software functions for health care providers certified under the ONC Health IT Certification Program, such as those that help track or manage patient immunizations by documenting the need for immunization, consent form, and immunization lot number;

14. Software functions that help asthmatics record (i.e., collect and log) inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks;

15. Software functions certified under the ONC Health IT Certification Program that prompt the health care provider to manually enter symptomatic, behavioral, or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for later review;

16. Software functions that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit;

17. Software functions that allow a user to record (i.e., collect and log) data, such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with a health care provider, or upload it to an online (cloud) database, or personal or electronic health record (PHR or EHR, respectively) that is certified under the ONC Health IT Certification Program;

18. Software functions that enable patients or health care providers to interact with PHR systems or EHR systems that are certified under the ONC Health IT Certification Program;

19. **Software functions that meet the definition of Non-Device-MDDS** – These are software functions that are solely intended to transfer, store, convert formats, and display medical device data or results, without controlling or altering the functions or parameters of any connected medical device. These include those software functions that are used as a secondary display to a regulated medical device when these apps are not intended to provide primary diagnosis or to be used to make treatment decisions, or software functions that are used in connection with active patient monitoring;

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40 Non-Device-MDDS is considered to be software functions that are solely intended to transfer, store, convert formats, and display medical device data or results, in accordance with the “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices” Guidance, available at [https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices).
20. **Software functions that display patient-specific medical device data** – These include software functions that display medical images directly from a Picture Archiving and Communication System (PACS) server;

21. **Software functions that are intended for transferring, storing, converting formats or displaying** clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results and findings.

   o Software functions that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (i.e., software functions that meet the definition of Non-Device-MDDS);
   o Software functions that meet the definition of Non-Device-MDDS and connect to a nursing central station and display (but do not analyze or interpret) medical device data to a physician’s mobile platform for review;
   o Software functions that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (e.g., rounds) or patient consultation (and include a persistent on-screen notice, such as “for informational purposes only and not intended for diagnostic use”).
Appendix B  Examples of Software Functions for which FDA intends to exercise enforcement discretion

This Appendix provides examples of software functions that MAY meet the definition of medical device but for which FDA intends to exercise enforcement discretion. These software functions may be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Even though this software MAY meet the definition of medical device, FDA intends to exercise enforcement discretion for these types of software functions because they pose lower risk to the public.

The FDA understands that there may be other unique and innovative software functions that may not be covered in this list that may also constitute health care related software. This list is not exhaustive; it is only intended to provide clarity and assistance in identifying the software functions that will not be subject to regulatory requirements at this time.

1. Software functions that help patients with diagnosed psychiatric conditions (e.g., post-traumatic stress disorder (PTSD), depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a “Skill of the Day” behavioral technique or audio messages that the user can access when experiencing increased anxiety;

2. Software functions that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women;

3. Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location;

4. Software functions that use video and video games to motivate patients to do their physical therapy exercises at home;

5. Software functions that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported;

6. Software functions that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling, and preventive recommendations from well-known and established authorities;

7. Software functions that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider;
8. Software functions that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of health care facility most appropriate to their needs;

9. Software functions that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology;

10. Software functions that enable a patient or caregiver to create and send an alert or general emergency notification to first responders;

11. Software functions that keep track of medications and provide user-configured reminders for improved medication adherence;

12. Software functions that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate);

13. Software functions that aggregate and display trends in personal health incidents (e.g., hospitalization rates or alert notification rates);

14. Software functions allow a user to collect (electronically or manually entered) blood pressure data and share this data through e-mail, track and trend it, or upload it to a personal or electronic health record;

15. Software functions that provide oral health reminders or tracking tools for users with gum disease;

16. Software functions that provide prediabetes patients with guidance or tools to help them develop better eating habits or increase physical activity;

17. Software functions that display, at opportune times, images or other messages for a substance abuser who wants to stop addictive behavior;

18. Software functions that provide drug-drug interactions and relevant safety information (side effects, drug interactions, active ingredient) as a report based on demographic data (age, gender), clinical information (current diagnosis), and current medications.
Appendix C  Examples of Software Functions that are the focus of FDA’s regulatory oversight (Device Software Functions and Mobile Medical Apps)

This Appendix provides examples of software functions that are considered medical devices (i.e., device software functions), and on which FDA will focus its regulatory oversight. This software meets the definition of a device under section 201(h) of the FD&C Act and its functionality poses a risk to a patient’s safety if the software were to not function as intended. Each example below provides a list of possible relevant product code(s) and/or regulation number.

FDA also encourages device software manufacturers to search FDA’s public databases, such as the “Product Classification” database and the “510(k) Premarket Notification” database, to determine the level of regulation for a given device and for the most up-to-date information about the relevant regulatory requirements.

Software functions (typically mobile apps) that transform a mobile platform into a regulated medical device and therefore are the focus of FDA’s regulatory oversight:

These mobile apps use a mobile platform’s built-in features such as light, vibrations, camera, or other similar sources to perform medical device functions (e.g., mobile medical apps that are used by a licensed practitioner to diagnose or treat a disease). Possible product codes: Varies depending on the intended use and software function; see additional examples below.

- Software functions that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG). Possible product code(s): DPS, MLC, OEW, OEY (21 CFR 870.2340), MLO, MWJ (21 CFR 870.2800).

- Software functions that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., microphone and speaker) to electronically amplify and “project sounds associated with the heart, arteries and veins and other internal organs” (i.e., an electronic stethoscope). Possible product code: DQD (21 CFR 870.1875(b)).

- Software functions that use a sensor or electrode attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer) to measure physiological parameters during cardiopulmonary resuscitation (CPR) and give feedback about the quality of CPR being delivered. Possible product code: LIX (21 CFR 870.5200).

- Software functions that use a sensor attached to the mobile platform or tools within the mobile platform itself to record, view, or analyze eye movements for use in the...

diagnosis of balance disorders (i.e., nystagmograph). Possible product code: GWN (21 CFR 882.1460).

- Software functions that use tools within the mobile platform (e.g., speaker) to produce controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders (i.e., an audiometer). Possible product code: EWO (21 CFR 874.1050).

- Software functions that use a sensor attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer) to measure the degree of tremor caused by certain diseases (i.e., a tremor transducer). Possible product code: GYD (21 CFR 882.1950).

- Software functions that use a sensor attached to the mobile platform or tools within the mobile platform itself (e.g., accelerometer, microphone) to measure physiological parameters (e.g., limb movement, electrical activity of the brain (EEG)) during sleep and are intended for use in diagnosis of specific diseases or conditions such as sleep apnea. Possible product code(s): OLV (21 CFR 882.1400), LEL, MNR (21 CFR 868.2375), FLS, NPF (21 CFR 868.2377).

- Software functions that use an attachment to the mobile platform to measure blood oxygen saturation for diagnosis of specific disease or condition. Possible product code(s): DQA, NLF, MUD, NMD (21 CFR 870.2700) or DPZ (21 CFR 870.2710).

- Software functions that present donor history questions to a potential blood donor and record and/or transmit the responses to those questions for a blood collection facility to use in determining blood donor eligibility prior to collection of blood or blood components. Possible product code: MMH (21 CFR 864.9165).

- Software functions that use an attachment to the mobile platform to measure blood glucose levels. Possible product code: NBW (21 CFR 862.1345).

- Software functions that use that use an attachment to the mobile platform (e.g., light source, laser) to treat acne, reduce wrinkles, or remove hair. Possible product code: OLP, OHT, OHS (21 CFR 878.4810), OZC (21 CFR 890.5740).

- Software functions that use a microphone or speaker within a mobile platform to serve as a audiometer to allow health care providers to determine hearing loss at different frequencies. Possible product code: EWO (21 CFR 874.1050).

- Software functions that analyze an image of a skin lesion using mathematical algorithms, such as fractal analysis, and provide the user with an assessment of the risk of the lesion.

Software functions that connect to an existing device type for purposes of controlling its operation, function, or energy source and therefore are the focus of FDA’s regulatory
**over sight:** These software functions are those that control the operation or function (e.g., changes settings) of an implantable or body worn medical device. Possible product codes: Varies depending on the intended use and function of the parent medical device; see additional examples below.

- Software functions that alter the function or settings of an infusion pump. Possible product codes: MEB, FRN, LZH, LZG, OPP, MEA (21 CFR 880.5725), FIH (21 CFR 876.5820), LKK.

- Software functions that act as wireless remote controls or synchronization devices for computed tomography (CT) or X-Ray machines. Possible product code: JAK (21 CFR 892.1750), IZL (21 CFR 892.1720), KPR (21 CFR 892.1680).

- Software functions that control or change settings of an implantable neuromuscular stimulator. Possible product code(s): GZC (21 CFR 882.5860).

- Software functions that calibrate, control, or change settings of a cochlear implant. Possible product code(s): MCM.

- Software functions that control the inflation or deflation of a blood-pressure cuff. Possible product code: DSJ (21 CFR 870.1100), DSK (21 CFR 870.1110), DXN (21 CFR 870.1130).

- Software functions that are used to calibrate hearing aids and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. Possible product code ETW (21 CFR 874.3310).

**Software functions that are used in active patient monitoring to analyze patient-specific medical device data and therefore are the focus of FDA’s regulatory oversight:**

- Software functions that acquire or process physiological signals that connect to bedside (or cardiac) monitors for active patient monitoring. Possible product code(s): DSI, MHX, MLD (21 CFR 870.1025), DRT, MWI, MSX (21 CFR 870.2300).

- Software functions that process uterine contraction and fetal heart rate data for remote monitoring of labor progress. Possible product code(s): HGM (21 CFR 884.2740).

- Software functions that are intended to process images for diagnostic review may be regulated as a picture archiving and communications system. Possible product code(s): LLZ (21 CFR 892.2050).
Appendix D  Examples of current regulations

This Appendix provides additional examples of classifications for regulated medical devices, the Class according to which they are regulated, and their regulation numbers as listed in Title 21 of the Code of Federal Regulations (CFR). This list is intended as a starting point for software manufacturers to assist them in identifying regulated medical devices.

In the table below -- Regulation Number 8xx.yyyy refers to regulation 21 CFR 8xx.yyyy; Device Class 1, 2, 3 – indicates the classification that applies to the device; Submission Type “510(k) exempt,” – means that the manufacturer is not required to submit a premarket notification (i.e., 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Submission type “510(k),” – means that the manufacturer is typically required to submit a premarket notification.

<table>
<thead>
<tr>
<th>Regulation number</th>
<th>Regulation Description</th>
<th>Example Device(s) within the Regulation (and current product code)</th>
<th>Device Class</th>
<th>Submission Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>862.1345</td>
<td>Glucose test system</td>
<td>System, Test, Blood Glucose, Over The Counter (NBW)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>862.2100</td>
<td>Calculator/data processing module for clinical use</td>
<td>Digital Image, Storage And Communications, Non-Diagnostic, Laboratory Information System (NVV)</td>
<td>1</td>
<td>510(k) exempt</td>
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<tr>
<td>868.1850</td>
<td>Monitoring spirometer</td>
<td>Spirometer, Monitoring (W/Wo Alarm) (BZK)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>868.1920</td>
<td>Esophageal stethoscope with electrical conductors</td>
<td>Stethoscope, Esophageal, With Electrical Conductors (BZT)</td>
<td>2</td>
<td>510(k)</td>
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<tr>
<td>868.2375</td>
<td>Breathing Frequency Monitor</td>
<td>Ventilatory Effort Recorder (MNR)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>868.2377</td>
<td>Apnea Monitor</td>
<td>Monitor, Apnea, Home Use (NPF)</td>
<td>2</td>
<td>510(k)</td>
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<tr>
<td>870.1025</td>
<td>Arrhythmia detector and alarm (including ST-segment measurement and alarm)</td>
<td>Detector and Alarm, Arrhythmia (DSI)</td>
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<td>510(k)</td>
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<tr>
<td>870.1110</td>
<td>Blood-Pressure Computer</td>
<td>Computer, Blood-Pressure (DSK)</td>
<td>2</td>
<td>510(k)</td>
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</table>
## Contains Nonbinding Recommendations

<table>
<thead>
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<th>Regulation number</th>
<th>Regulation Description</th>
<th>Example Device(s) within the Regulation (and current product code)</th>
<th>Device Class</th>
<th>Submission Type</th>
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</thead>
<tbody>
<tr>
<td>870.1130</td>
<td>Noninvasive blood pressure measurement system</td>
<td>System, Measurement, Blood-Pressure, Non-Invasive (DXN)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>870.1875(b)</td>
<td>Stethoscope</td>
<td>Lung Sound Monitor (OCR) Stethoscope, Electronic (DQD)</td>
<td>2</td>
<td>510(k) exempt</td>
</tr>
<tr>
<td>870.2300</td>
<td>Cardiac Monitor (including cardiotachometer and rate alarm)</td>
<td>Monitor, Cardiac (Incl. Cardiotachometer &amp; Rate Alarm) (DRT) Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) (MWI) System, Network And Communication, Physiological Monitors (MSX)</td>
<td>2</td>
<td>510(k)</td>
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<tr>
<td>870.2340</td>
<td>Electrocardiograph</td>
<td>Monitor, St Segment (MLC) Single Lead Over-the-Counter Electrocardiograph (OEY)</td>
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<td>510(k)</td>
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<tr>
<td>870.2700</td>
<td>Oximeter</td>
<td>Oximeter (DQA)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>870.2770</td>
<td>Impedance plethysmograph</td>
<td>Analyzer, Body Composition (MNW)</td>
<td>2</td>
<td>510(k)</td>
</tr>
<tr>
<td>870.2800</td>
<td>Medical magnetic tape recorder</td>
<td>Electrocardiograph, Ambulatory, With Analysis Algorithm (MLO) Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection) (MXC)</td>
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<tr>
<td>874.1050</td>
<td>Audiometer</td>
<td>Audiometer (EWO)</td>
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<td>874.3400</td>
<td>Tinnitus masker</td>
<td>Masker, Tinnitus (KLW)</td>
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<td>874.4770</td>
<td>Otoscope</td>
<td>Otoscope (ERA)</td>
<td>1</td>
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<tr>
<td>876.1500</td>
<td>Endoscope and accessories</td>
<td>Endoscopic Video Imaging System/Component, Gastroenterology-Urology (FET)</td>
<td>2</td>
<td>510(k)</td>
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<tr>
<td>876.1725</td>
<td>Gastrointestinal motility monitoring system</td>
<td>Recorder, External, Pressure, Amplifier &amp; Transducer (FES)</td>
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<tr>
<td>Regulation number</td>
<td>Regulation Description</td>
<td>Example Device(s) within the Regulation (and current product code)</td>
<td>Device Class</td>
<td>Submission Type</td>
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<tr>
<td>878.4160</td>
<td>Surgical camera and accessories</td>
<td>Camera, Cine, Microsurgical, With Audio (FWK) Camera, Still, Microsurgical (FTH) Camera, Television, Endoscopic, With Audio (FWG)</td>
<td>1</td>
<td>510(k) exempt</td>
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<td></td>
<td></td>
<td></td>
<td>1</td>
<td>510(k) exempt</td>
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<td></td>
<td>1</td>
<td>510(k) exempt</td>
</tr>
<tr>
<td>878.4810</td>
<td>Laser surgical instrument for use in general and plastic surgery and in dermatology</td>
<td>Light Based Over The Counter Wrinkle Reduction (OHS) Over-The-Counter Powered Light Based Laser For Acne (OLP)</td>
<td>2</td>
<td>510(k)</td>
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<td>510(k)</td>
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<td>Monitor, Bed Patient (KMI)</td>
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<td>510(k) exempt</td>
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<td>880.2700</td>
<td>Stand-on patient scale</td>
<td>Scale, Stand-On, Patient (FRI)</td>
<td>1</td>
<td>510(k) exempt</td>
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<tr>
<td>880.2910</td>
<td>Clinical electronic thermometer</td>
<td>Thermometer, Electronic, Clinical (FLL)</td>
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<td>880.5580</td>
<td>Acupuncture needle</td>
<td>Locator, Acupuncture Point (BWJ)</td>
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<td>880.6350</td>
<td>Battery-powered medical examination light</td>
<td>Light, Examination, Medical, Battery Powered (KYT)</td>
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<td>510(k) exempt</td>
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<td>882.1400</td>
<td>Electroencephalograph</td>
<td>Full-montage electroencephalograph (GWQ) Standard polysomnograph with electroencephalograph (OLV)</td>
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<tr>
<td>882.1550</td>
<td>Nerve conduction velocity measurement device</td>
<td>Device, Nerve conduction velocity measurement (JXE)</td>
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<td>510(k)</td>
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<td>882.1620</td>
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<td>Device, Monitoring, Intracranial pressure (GWM)</td>
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<td>882.1890</td>
<td>Evoked response photic stimulator</td>
<td>Stimulator, Photic, Evoked response (GWE)</td>
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<td>882.1900</td>
<td>Evoked response auditory stimulator</td>
<td>Stimulator, Auditory, Evoked response (GWJ)</td>
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<td>Tremor transducer</td>
<td>Transducer, Tremor (GYD)</td>
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<td>884.2730</td>
<td>Home uterine activity monitor</td>
<td>Monitor, Heart Rate, Fetal, Non-Stress Test (Home Use) (MOH)</td>
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<td>510(k)</td>
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<tr>
<td>884.2740</td>
<td>Perinatal monitoring system and accessories</td>
<td>System, Monitoring, Perinatal (HGM)</td>
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<td>Regulation number</td>
<td>Regulation Description</td>
<td>Example Device(s) within the Regulation (and current product code)</td>
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<td>System, Monitoring, For Progress Of Labor (NPB)</td>
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<td>884.2900</td>
<td>Fetal stethoscope</td>
<td>Stethoscope, Fetal (HGN)</td>
<td>1</td>
<td>510(k) exempt</td>
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<td>884.6120</td>
<td>Assisted reproductive accessories</td>
<td>Accessories, Assisted Reproduction (MQG)</td>
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<td>884.6190</td>
<td>Assisted reproductive microscopes and microscope accessories</td>
<td>Microscope And Microscope Accessories, Reproduction, Assisted (MTX)</td>
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<tr>
<td>886.1510</td>
<td>Eye movement monitor</td>
<td>Monitor, Eye Movement, Diagnostic (HMC)</td>
<td>2</td>
<td>510(k)</td>
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<td>886.1570</td>
<td>Ophthalmoscope</td>
<td>Ophthalmoscope, Battery-powered (HLJ)</td>
<td>2</td>
<td>510(k) exempt</td>
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<tr>
<td>886.1930</td>
<td>Tonometer and accessories</td>
<td>Tonograph (HPK)</td>
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<td>886.5540</td>
<td>Low-vision magnifier</td>
<td>Magnifier, Hand-Held, Low-Vision (HJF) Spectacle Microscope, Low-Vision (HKC)</td>
<td>1</td>
<td>510(k) exempt</td>
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<tr>
<td>892.1560</td>
<td>Ultrasonic pulsed echo imaging system</td>
<td>System, Imaging, Optical Coherence Tomography (Oct) (NQQ)</td>
<td>2</td>
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<td>892.2030</td>
<td>Medical image digitizer</td>
<td>Digitizer, Image, Radiological (LMA) Digitizer, Images, Ophthalmic (NFH)</td>
<td>2</td>
<td>510(k) exempt</td>
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<tr>
<td>892.2050</td>
<td>Picture archiving and communications system</td>
<td>System, Image Processing, Radiological (LLZ) System, Image Management, Ophthalmic (NFJ)</td>
<td>2</td>
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Appendix E  Brief description of certain device regulatory requirements

This Appendix provides a high level description of certain regulatory requirements for medical devices, including device software functions. The FDA has additional resources and publications online that describe these and other requirements in detail.

1. Establishment Registration and Medical Device Listing

Under 21 CFR Part 807, manufacturers of medical devices are required to annually register their establishments with FDA and provide a list of the devices they market. The registration and listing requirement is a means of keeping FDA advised of who is manufacturing devices, and of the types of devices an establishment is manufacturing. Medical device manufacturers are required to register their establishments with FDA and to list by identifying to FDA the devices they are marketing.

Additional information can be found in “Device Advice: Device Registration and Listing.” If you need further assistance, you may contact the Division of Risk Management Operations, Regulatory Policy and Systems Branch: Email: reglist@fda.hhs.gov, phone: 301-796-7400. Assistance is also available from, Division of Industry and Consumer Education (DICE): Email: DICE@fda.hhs.gov, phone: 301-796-7100 or 800-638-2041.

2. Investigational Device Exemption (IDE) requirements

An IDE allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

Medical device manufacturers who are creating software with novel technologies are encouraged to engage in early collaboration meetings with the FDA to receive recommendations for testing and development of those devices requiring clinical investigations to support marketing.

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43 Under 21 CFR 807.3(e), “Establishment” is defined as “a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed.”

44 See 21 CFR Part 807.

Additional information about these meetings is described in guidance issued on February 28, 2001: “Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff.”

Further information regarding the investigational device exemption can be found in “Device Advice: Investigational Device Exemption.”

3. Labeling requirements

Medical device manufacturers are required to comply with applicable labeling regulations found in 21 CFR Part 801 for medical devices and 21 CFR Part 809 for in vitro diagnostic products.

4. Premarket submission for approval or clearance

Medical device manufacturers should identify the current classification covering their device. Manufacturers are required to prepare and submit to the FDA an appropriate premarket submission, as required for their device classification.

Additional information can be found in “Device Advice: Device Registration and Listing.”

5. Quality System Regulation (QS Regulation)

Medical device manufacturers are required to comply with the QS regulation. The QS regulation does not prescribe in detail how a manufacturer must produce a specific device, but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. As part of this framework, manufacturers are required to develop requirements for their products that will result in devices that are safe and effective, and to establish methods and procedures to design, produce, and distribute their devices.

Furthermore, manufacturers are required, as part of the QS regulation (21 CFR 820.30), to appropriately verify and validate their device software functions along with the computing platform to ensure safe and effective operation of the device.

Manufacturers are required to ensure that adequate controls and processes are in place through purchasing controls to ensure safe distribution, installation, and operation of the device software function.

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49 See 21 CFR Part 820.
6. Medical Device Reporting (MDR) (Adverse event reporting)

The Medical Device Reporting (MDR) regulation requires manufacturers and importers of medical devices to submit reports to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device they market may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that they market would be likely to cause or contribute to a reportable death or serious injury if the malfunction were to recur.\(^51\) MDR requires medical device manufacturers to:

- Submit MDR reportable events involving their medical devices as described in 21 CFR 803.10(c) and 803.50;
- Submit 5-day reports as described in 21 CFR 803.53;
- Submit supplemental reports as described in 21 CFR 803.56;
- Develop, maintain, and implement written procedures for the identification and evaluation of all medical device events to determine whether the event is MDR reportable as described in 21 CFR 803.17;
- Conduct an investigation of each event and evaluate the cause of the event as described in 21 CFR 803.50(b)(3); and
- Establish and maintain complete files for all complaints concerning adverse medical device events as described in 21 CFR 803.18.

The MDR report (FDA Form 3500A) must contain all the information described in 21 CFR 803.52 that is reasonably known to the manufacturer. Information reasonably known includes any information that:

- Can be obtained by contacting a user facility, importer, or other initial reporter;
- Is in the possession of the manufacturer; or
- Can be obtained by analysis, testing, or other evaluation of the device.

For additional instructions on how to complete the 3500A form, refer to the document titled “Instructions for Completing Form FDA 3500A.”\(^52\)

For additional guidance on the MDR regulation and the reporting requirements, refer to the document titled “Medical Device Reporting for Manufacturers.”\(^53\)

\(^{50}\) Available at https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system qs-regulationmedical-device-good-manufacturing-practices.

\(^{51}\) See 21 CFR Part 803.

\(^{52}\) Available at https://www.fda.gov/safety/forms-reporting-fda/instructions-completing-form-fda-3500.

\(^{53}\) Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-reporting-manufacturers.
Contains Nonbinding Recommendations

For Questions about Medical Device Reporting, including interpretation of MDR policy:

- Call: (301) 796-6670 (voice)
- Email: RSMB@fda.hhs.gov
- Mail: Food and Drug Administration, Center for Devices and Radiological Health, Reporting Systems Monitoring Branch, 10903 New Hampshire Avenue, WO Bldg. 66, Room 3217, Silver Spring, MD 20993-0002

7. Correcting Problems

A medical device manufacturer may voluntarily take action at any time or may be requested to take action by the FDA to correct problems. Voluntary action is usually taken by device manufacturers. Examples of the types of actions that a device manufacturer may be requested to take include, but are not limited to:

- Inspecting the device for problems;
- Repairing the device;
- Adjusting settings on the device; and
- Upgrading software to reduce risk from a “bug” or unintended response.

Under certain circumstances, FDA may initiate a request that a manufacturer address a problem with a device through other means, including by removal of the product from the market. When recommending corrective action, the FDA intends to take into account the essential role that certain device software functions take as an integral part of a larger patient care system.

Reporting Corrections to FDA:

In accordance with 21 CFR 806.10, medical device manufacturers are required to promptly report, within 10 working days from the time the correction is initiated, to the FDA certain actions concerning device corrections and removals. Specifically, medical device manufacturers are required to report to FDA any corrections made to a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a risk to health.

The reporting requirement does not extend to all modifications to devices. For example, certain actions that would improve the quality of a mobile medical app but that would not reduce a risk to health posed by the mobile medical app or remedy a violation of the FD&C Act are not required to be reported under 21 CFR 806.1(b). If there is not a "risk to health"

54 Under 21 CFR 806.1(b), the following actions are exempt from the reporting requirements of Part 806:
(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.
(2) Market withdrawals as defined in 21 CFR 806.2(h).
(3) Routine servicing as defined in 21 CFR 806.2(k).
(4) Stock recoveries as defined in 21 CFR 806.2(l).
involved, a report to FDA is not required, but the device manufacturer must keep a record of the correction. An example of such action taken by the manufacturer could be changes made to correct a defect that creates a nuisance for the user but does not present a risk to the health of the user or patient.

More information about reporting requirements under 21 CFR Part 806 is available in “Device Advice: Recalls, Corrections, and Removals.”

Appendix F  Frequently Asked Questions (FAQs)

1) I have a software function that is not identified in this guidance. What is the best way to get additional information from the FDA about my product?

Answer: FDA recognizes that this guidance does not describe all types of software used in health care. Some manufacturers may be unsure whether their software function is considered a medical device that is subject to regulatory oversight, or whether their medical device could be under FDA’s intent to exercise enforcement discretion. If the device is subject to regulatory oversight, manufacturers may have questions about which regulatory requirements are applicable to their software function.

After reviewing this guidance, FDA encourages software manufacturers to contact the Agency to obtain more information using one of the following ways:

- **Phone or e-mail** – For information about regulatory requirements, contact the Division of Industry and Consumer Education (DICE). Email: DICE@fda.hhs.gov; phone: 301-796-7100 or 800-638-2041.
  For information about whether your software or mobile app is considered a medical device, contact digitalhealth@fda.hhs.gov.
  If your question relates to apps used in blood establishments or another area of CBER regulation, contact the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring; e-mail: ocod@fda.hhs.gov; phone: 1-800-835-4709 or 240-402-7800.

- **Online** – The FDA has several resources and publications online that describe various regulatory requirements in detail. FDA’s “Device Advice” website and online courses at “CDRH Learn” are a good place to start. Other sections in this guidance provide links to more detailed information related to more specific topics.

- **Letter** – For written feedback about the classification and the regulatory requirements that may be applicable to a device software function, manufacturers should use the 513(g) process. Specifically, a manufacturer should submit the following for a 513(g) submission:
  - User fee;
  - Cover letter;
  - Description of the software;
  - Description of what the software is to be used for; and
  - Any proposed labeling or promotional material for the software and, as applicable, any labeling or promotional material of a similar, legally marketed device, if available.

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56 Available at [https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance](https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance).

FDA will generally issue a response to the 513(g), in the form of a confidential letter to the manufacturer, within 60 days of receipt of the request for information. For more specific information about what to include in a 513(g) and where to send it, refer to FDA’s guidance document titled “FDA and Industry Procedures for Section 513(g) Requests for Information Contains Nonbinding Recommendations Under the Federal Food, Drug, and Cosmetic Act.” For more information about 513(g) user fees, refer to FDA’s guidance document titled “User Fees for 513(g) Requests for Information.”

2) Why does FDA recommend that manufacturers follow the Quality System (QS) regulation for those software that MAY be devices and could be device software functions but for which FDA intends to exercise enforcement discretion?

Answer: FDA believes all manufacturers of medical device software should have in place an adequate quality management system that helps ensure that their products consistently meet applicable requirements and specifications and can support the software throughout its total life cycle. Adequate quality management systems incorporate appropriate risk management strategies, good design practices, adequate verification and validation, and appropriate methods to correct and prevent risks to patients and adverse events that may arise from the use of the product. All of these elements are part of FDA’s QS regulation.

3) Is FDA’s QS regulation similar to software development practices I already use?

Answer: Most likely. Though not all of the principles in the QS regulation are applicable to the development and manufacture of quality device software functions, the majority of them are applicable and are consistent with commonly used and accepted good software development practices, such as those from the Institute of Electrical and Electronics Engineers’ (IEEE), Software Engineering Body of Knowledge (SWEBOK), and Carnegie Mellon Software Engineering Institute’s Capability Maturity Model Integration (CMMI) methods.

The FDA’s approach to QS regulation is also harmonized with certain international standards such as ISO 9001 and ISO 13485. Similar to these international standards, the QS regulation does not prescribe in detail how a manufacturer must produce a specific device, but provides a framework for all manufacturers to develop and follow to help ensure that their products consistently meet applicable requirements and specifications. The QS regulation can apply to and be scaled for any size manufacturer and any type of product. It

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59 Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information.

60 Certain portions of the QS regulation that apply to medical device hardware (such as the production and process controls outlined in 21 CFR 820.70) may not clearly apply to device software functions.

also allows for a manufacturer to choose those requirements most appropriate for its given
device and manufacturing process.  

4) **What are some examples of parts of the QS regulation that are of particular
importance to device software functions and where can I find more information
about them?**

**Answer:** Though not a complete list, some examples of principles within the QS regulation
that are relevant to all device manufacturers include risk assessment and management, design
controls, and corrective and preventive actions. Risk assessment and management is a critical
part of good quality management systems. Good design practices are important to the
development and manufacture of safe medical devices. It is also important for manufacturers
to have procedures in place to identify, analyze, correct, and prevent software-related causes
of patient or user harm. References related to these examples are provided in Appendix E of
this guidance. Additional references about these principles that manufacturers may find
useful include the following:

FDA’s “Design Control Guidance for Medical Device Manufacturers,” available at
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-
guidance-medical-device-manufacturers.

FDA’s “General Principles of Software Validation” guidance, available at
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-
principles-software-validation.

5) **Do all the device software function manufacturers have to submit a premarket
submission and receive FDA clearance or approval before marketing?**

**Answer:** No, not all manufacturers have to submit a premarket submission (i.e., a 510(k) or
PMA) prior to marketing their device software function. This determination depends on the
classification of the device. Manufacturers of devices that are exempt from 510(k) or PMA
requirements do not have to file a submission with FDA prior to marketing their device. For
example, the majority of class I devices are exempt from the premarket submission
requirements and are subject to the least regulatory control.

Regardless of whether medical devices are subject to the premarket submission requirements,
most medical devices (including Class I devices) have to comply with other basic regulatory
requirements that are called “General Controls.” More information about what “General
Controls” are and what a medical device manufacturer should do to comply with these
requirements, can be found in “Device Advice: General Controls for Medical Devices” and
“Regulatory Controls.”

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62 See 21 CFR 820.1 (stating “if a manufacturer engages in only some operations subject to the requirements in
this part, and not in others, that manufacturer need only comply with those requirements applicable to the
operations in which it is engaged.”).

63 Available at https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices and
6) Some FDA classifications state they are “510(k) exempt.” What does 510(k) exempt mean and how do I know if it applies to my product?

Answer: If a classification states the device type is “510(k) exempt,” this means that the manufacturer is not required to submit a premarket notification (i.e., a 510(k)) prior to marketing the device. However, the 510(k) exemption may be subject to certain limitations. Manufacturers are encouraged to confirm the device’s exempt status and any limitations to that status that may apply in accordance with 21 CFR Parts 862-892. Additional information about 510(k) exempt devices can be found at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm.

7) If a 510(k) is required for my device software function, what type of software documentation does FDA recommend I include in the submission?

Answer: FDA’s recommendations for the software-related documentation that you provide in your premarket submission are addressed in detail in the FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

If the device software function uses off-the-shelf software, manufacturers should also refer to FDA’s “Guidance for Industry, FDA Reviewers, and Compliance on Off-the-Shelf Software Use in Medical Devices.”

8) I am a medical device manufacturer and making my product labeling available electronically using a mobile app. Is my app considered a mobile medical app?

Answer: Mobile apps that provide electronic access and are intended for use as a digital version of medical device labeling or instructions for use are not considered a medical device on their own and therefore are not considered mobile medical apps. These are apps from a device manufacturer that provide information to support the company’s own device. Examples include apps that provide an electronic copy of cleared or approved medical device labeling or apps that provide video instruction for how to use a medical device. These types of apps are not considered devices within themselves, but instead are considered part of the medical device labeling and are subject to the regulatory labeling requirements relevant to that particular product.

9) Is an electronic method of collecting clinical investigations, for example through a mobile app, considered a device software function, and if so, what requirements apply?

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Answer: Software used for data collection in clinical studies (such as electronic Patient Reported Outcomes (ePRO) apps) is not considered on its own to be a device software function. However, manufacturers and users of this type of software should see FDA’s guidance related to use of computers in clinical trials, “Electronic Source Data in Clinical Investigations,” issued on September 17, 2013.

10) I am a medical device manufacturer. Is an electronic method of collecting and storing quality systems information in my manufacturing process considered a medical device?

Answer: Software used in the production process for medical devices, or for collecting, storing and maintaining quality system data collection for medical devices (including complaint submissions) is not considered a medical device on its own. This software does not meet the definition of medical device but is part of the quality system. However this software is required to comply with the appropriate good manufacturing practices (GMP) regulations (see 21 CFR Part 820).

Appendix G  Additional Resources

A.  Guidance Documents


B.  Standards

AAMI = Association for the Advancement of Medical Instrumentation
ANSI = American National Standards Institute
IEC = International Electrotechnical Commission
IEEE = Institute of Electrical and Electronics Engineers
ISO = International Organization for Standardization


3. ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.


5. ISO 14971 Medical devices — Application of risk management to medical devices.

6. IEC 62304 Medical device software – Software life cycle processes.

8. ISO/IEC 25051 Software engineering – Systems and software product Quality Requirements and Evaluation (SQuaRE) – Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing.


10. AAMI TIR36 Validation of software for regulated processes.


12. ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (particularly clause 14).

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2014-N-1039. Comments may not be acted upon by the Agency until the document is next revised or updated.

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General Wellness:  
Policy for Low Risk Devices  

Guidance for Industry and 
Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance document to provide clarity to industry and FDA staff on the Center for Devices and Radiological Health’s (CDRH’s) compliance policy for low risk products that promote a healthy lifestyle (general wellness products).1 This guidance does not apply to products (e.g., drugs, biologics, dietary supplements, foods, or cosmetics) regulated by other FDA Centers or to combination products.2

Section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions, including those intended for maintaining or encouraging a healthy lifestyle that are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, from the definition of device in section 201(h) of the FD&C Act. Section 520(o)(1)(B) of the FD&C Act, states that software that is intended “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition” is not a device under section 201(h) of the FD&C Act.

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1 This guidance does not change or rescind any requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or any applicable regulations. This guidance also does not preclude FDA from consulting with the Consumer Product Safety Commission (CPSC) as to whether a general wellness product is a consumer product under CPSC’s authority or a device. FDA may coordinate with other agencies and authorities, such as the CPSC, to determine jurisdiction over products. If a product is a device under section 201(h) of the FD&C Act, it is generally excluded from CPSC’s authority over “consumer products” under the Consumer Product Safety Act (15 U.S.C. § 2052(a)(5)(ii)(H)). However, CPSC and FDA may both have jurisdiction over certain medical devices under other statutory authorities the CPSC administers.

2 For determinations on combination products, contact the Office of Combination Products at combination@fda.gov. See 21 CFR 3.2(e) for the definition of a combination product.
This guidance clarifies FDA’s interpretation of this provision and its application to general wellness products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

II. Policy on Low Risk General Wellness Products

CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act and implementing regulations, including, but not limited to: registration and listing and premarket notification requirements (21 CFR Part 807); labeling requirements (21 CFR Part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803).

For purposes of this guidance, CDRH defines general wellness products as products that meet the following two factors: (1) are intended for only general wellness use, as defined in this guidance, and (2) present a low risk to the safety of users and other persons. General wellness products may include exercise equipment, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the two factors above.

CDRH regularly receives inquiries about whether particular products are devices as defined by the FD&C Act. There are instances where certain general wellness products, as discussed in this guidance, do not meet the definition of a device under section 201(h) of the FD&C Act and therefore are not subject to the FD&C Act’s regulatory requirements for devices. Additionally, section 520(o)(1)(B) of the FD&C Act excludes software functions that are intended for maintaining or encouraging a healthy lifestyle and are unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition from the definition of

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3 The term “device” is defined in 201(h) of the FD&C Act to include an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is …intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man … or intended to affect the structure or any function of the body of man...” and “does not include software functions excluded pursuant to section 520(o) of the FD&C Act.”

A product's inclusion under the general wellness policy in this guidance does not establish that it has been shown to be safe and/or effective for its intended use.

### III. General Wellness Products

A **general wellness product**, for the purposes of this guidance, has (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

If the product’s intended uses are not limited to the above general wellness intended uses, this guidance does not apply.

The first category of general wellness intended uses involve claims about sustaining or offering general improvement to functions associated with a general state of health that **do not make any reference to diseases or conditions**. For the purposes of this guidance, this first category of general wellness claims relate to:

- weight management,
- physical fitness, including products intended for recreational use,
- relaxation or stress management,
- mental acuity,
- self-esteem (e.g., devices with a cosmetic function that make claims related only to self-esteem),
- sleep management, or
- sexual function.

The following are examples of this category of general wellness claims:

- Claims to promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals;
- Claims to promote relaxation or manage stress;
- Claims to increase, improve, or enhance the flow of qi “energy”;
- Claims to improve mental acuity, instruction following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition, or eye-hand coordination;

---

5 “Nothing in this subsection shall be construed as limiting the authority of the [FDA] to— (A) exercise enforcement discretion as to any device subject to regulation under this Act . . .” (section 520(o)(4) of the FD&C Act).
Contains Nonbinding Recommendations

- Claims to enhance learning capacity;
- Claims to promote physical fitness, such as to help log, track, or trend exercise activity, measure aerobic fitness, improve physical fitness, develop or improve endurance, strength or coordination, or improve energy (e.g., “fitness” or “activity” trackers);
- Claims to promote sleep management, such as to track sleep trends;
- Claims to promote self-esteem, such as to boost self-esteem;
- Claims that address a specific body structure or function, such as to increase or improve muscle size or body tone, tone or firm the body or muscle, or enhance or improve sexual performance;
- Claims to improve general mobility or to assist individuals who are mobility impaired in a recreational activity (e.g., sport wheelchairs, beach access wheelchairs); and
- Claims to enhance an individual’s participation in recreational activities by monitoring the consequences of participating in such activities, such as to monitor heart rate or monitor frequency or impact of collisions.

The following are examples of claims that do not fall into this category of general wellness claims:

- A claim that a product will treat or diagnose obesity;
- A claim that a product will treat an eating disorder, such as anorexia;
- A claim that a product helps treat an anxiety disorder;
- A claim that a computer game will diagnose or treat autism;
- A claim that a product will treat muscle atrophy or erectile dysfunction; and
- A claim to restore a structure or function impaired due to a disease or condition, e.g., a claim that a prosthetic device enables amputees to walk.6

The second category of general wellness intended uses relate to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions. For the purposes of this guidance, this second category of general wellness claims is comprised of two subcategories:

1) intended uses to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions; and

2) intended uses to promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, may help living well with certain chronic diseases or conditions.

Both subcategories of disease-related general wellness claims should only be based on references where it is well understood that healthy lifestyle choices may reduce the risk or

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6 Products intended to restore a structure or function impaired due to a disease might be regulated by FDA as devices. For example, an artificial limb prosthesis intended to provide disabled persons the ability to walk might be regulated under 21 CFR 890.3420 or 21 CFR 890.3500.
impact of a chronic disease or medical condition. That is, the claim that the healthy lifestyle choice(s) may play an important role in health outcomes should be generally accepted; such associations are described in peer-reviewed scientific publications or official statements made by healthcare professional organizations. Examples of chronic diseases for which a healthy lifestyle is associated with risk reduction or help in living well with that disease include heart disease, high blood pressure, and type 2 diabetes.

The following are examples of this category of disease-related general wellness claims:

- Software Product U coaches breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches.
- Software Product V tracks and records your sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety.
- Product W promotes making healthy lifestyle choices such as getting enough sleep, eating a balanced diet, and maintaining a healthy weight, which may help living well with type 2 diabetes.
- Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.
- Software Product Y tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet. Healthy weight and balanced diet may help living well with high blood pressure and type 2 diabetes.
- Product Z tracks activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes.

IV. Determining Risk for General Wellness Products

CDRH’s general wellness policy applies only to general wellness products that are low risk. If the answer to any of the following questions is YES, the product is not low risk and is not covered by this guidance.

1) Is the product invasive?
2) Is the product implanted?
3) Does the product involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure?

In assessing whether a product is low risk for purposes of this guidance, FDA recommends that you also consider whether CDRH actively regulates products of the same type as the

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7 By organizations we mean associations and colleges such as American Medical Association (AMA), American Heart Association (AHA), American Association of Clinical Endocrinologists (AACE), American College of Rheumatology, etc.
8 Whether a device is classified as class I under section 513(a)(1) of the FD&C Act does not necessarily mean that it is “low risk” for purposes of this guidance.
9 For purposes of this guidance, “invasive” means penetrates or pierces the skin or mucous membranes of the body.
product in question. For example, CDRH actively regulates external penile rigidity devices, which are devices intended to create or maintain sufficient penile rigidity for sexual intercourse, under 21 CFR 876.5020 as class II devices exempt from premarket notification with special controls. The special controls for these devices address risks to health that are associated with the use of these devices, including, without limitation, tissue injury, trauma or infection. Therefore, these types of devices would not be considered low risk general wellness products.

The following are examples of products that would not be considered “low risk” as described in this guidance:

- Sunlamp products promoted for tanning purposes, due to risks to a user’s safety from the ultraviolet radiation, including, without limitation, an increased risk of skin cancer.
- Implants promoted for improved self-image or enhanced sexual function. Implants pose risks to users such as rupture or adverse reaction to implant materials and risks associated with the implantation procedure.
- A laser product that claims to improve confidence in user’s appearance by rejuvenating the skin. Although the claims of rejuvenating the skin and improving confidence in user’s appearance are general wellness claims, laser technology presents risks of skin and eye burns.
- A neurostimulation product that claims to improve memory, due to the risks to a user’s safety from electrical stimulation.
- A product that claims to enhance a user’s athletic performance by providing suggestions based on the results of relative lactic acid testing, when the product uses venipuncture to obtain the blood samples needed for testing. Such a product is not low risk because it is invasive (e.g., obtains blood samples by piercing the skin) and also because the product involves an intervention that may pose a risk to the safety of the user and other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).

V. Examples of General Wellness Products that Are Not Medical Devices and Examples of General Wellness Products that Are Medical Devices for which FDA Does Not Intend to Enforce Requirements

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Illustrative Example 1: A software function plays music to “soothe and relax” an individual and to “manage stress.” Such a software function is not a device function.

This software function has claims that relate only to relaxation or stress management, not to any disease or medical condition, and thus are general wellness claims. In addition, the technology to play music does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 2: A software function that solely monitors and records daily energy expenditure and cardiovascular workout activities to “allow awareness of one’s exercise activities to improve or maintain good cardiovascular health.” Such a software function is not a device function.

This software function has a claim that relates to a specific organ only in the context of general health and does not refer to a disease or medical condition. In addition, although the monitoring or recording of exercise activities present risks (such as inaccuracy), when made in the absence of disease or medical condition claims, the technology does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 3: A software function monitors and records food consumption to “manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity.” Such a software function is not a device function.

This software function has a claim that relates to dietary choices and weight management, and thus is a general wellness claim. In addition, the technology for monitoring or recording food consumption does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 4: A software function that reminds users to keep exposed skin out of direct sunlight when the UV index is high, which, as part of a healthy lifestyle, may help reduce the risk of skin cancer.

This claim relates to tracking preventive measures which, as part of a healthy lifestyle, may help reduce the risk of a medical condition. The claim is for a healthy lifestyle choice and it is generally accepted that the choice may play an important role in health outcomes. Thus, it is a general wellness claim. In addition, the technology reminding users to keep exposed skin out of direct sunlight does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.
Illustrative Example 5: A portable product that is intended to monitor the pulse rate of users during exercise and hiking.

This claim relates only to exercise and hiking and does not refer to a disease or medical condition. Thus, it is a general wellness claim. In addition, the technology for monitoring pulse rate does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Illustrative Example 6: A product is intended to mechanically exfoliate the face, hands and feet to make the skin smoother and softer. The product cannot be used in a manner that penetrates or pierces the skin.

This claim relates to self-esteem and does not refer to a specific disease or medical condition, and thus is a general wellness claim. In addition, the product is noninvasive as it does not penetrate the stratum corneum and the technology for exfoliating the face does not pose a risk to the safety of users and other persons if specific regulatory controls are not applied. Therefore, this product meets both factors for a low risk general wellness product.

Note: However, if the product is intended to exfoliate the skin in order to enhance the delivery of a topically applied product containing one or more active pharmaceutical ingredients through the stratum corneum, the product would be invasive. Therefore, the product would not be a low risk general wellness product.

VI. Determining whether General Wellness Products are within Scope of the Guidance

The following questions reflect the framework described in this guidance to determine whether general wellness products are within the scope of the guidance. Please note that these questions are intended to be addressed in the context of the full text of the guidance.

A1. Does the product have an intended use that relates to maintaining or encouraging a general state of health or a healthy activity?

Does the product only involve claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions? Claims in this category include: weight management, physical fitness, relaxation or stress management, mental acuity, self-esteem, sleep management, or sexual function.

<table>
<thead>
<tr>
<th>YES</th>
<th>Go to A3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>Go to A2.</td>
</tr>
</tbody>
</table>
A2. **Does the product have an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions?** *(In answering this question, the following two questions must be considered together.)*

a) Does the product have an intended use that relates to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions, and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition?

**AND**

b) Is the relation between healthy lifestyle and disease specifically expressed as “**may help to reduce the risk of**,” or “**may help living well with**,” a chronic disease or condition?

<table>
<thead>
<tr>
<th>YES ⇒</th>
<th>Go to A3. Both questions A2(a) and A2(b) must be answered “Yes” in order to proceed to question A3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO ⇒</td>
<td>Product is <strong>NOT</strong> a low risk general wellness product, and is <strong>outside the scope of this guidance.</strong></td>
</tr>
</tbody>
</table>

A3. **Is the product low risk?**

Is the product not invasive, and not implanted, and does not involve a technology that may pose a risk to the safety of users or other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure? *(In answering this question, consider whether CDRH actively regulates products of the same type as the product in question.)*

<table>
<thead>
<tr>
<th>YES ⇒</th>
<th>The product is likely a general wellness product within the scope of this guidance, but the factors and examples in the guidance should be reviewed to confirm the status of the product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO ⇒</td>
<td>Product is <strong>NOT</strong> a low risk general wellness product, and is <strong>outside the scope of this guidance.</strong></td>
</tr>
</tbody>
</table>
FDA has updated this guidance consistent with the definition of “device” in section 201(h) of the Federal Food, Drug, and Cosmetic Act, as amended by the 21st Century Cures Act, and the final guidance, “Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act.” FDA also has made minor updates to terminology and citations throughout. Following this update, FDA will assess how to update and revise this guidance to better reflect our current thinking on this topic.
Off-The-Shelf Software Use in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2019.


For questions about this document, contact the Division of Digital Health by e-mail at digitalhealth@fda.hhs.gov.
Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2019-D-3598. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Off-The-Shelf Software Use in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

Off-the-shelf (OTS) Software is commonly being considered for incorporation into medical devices as the use of general-purpose computer hardware becomes more prevalent. The use of OTS Software in a medical device allows the manufacturer to concentrate on the application software needed to run device-specific functions. However, OTS Software intended for general-purpose computing may not be appropriate for a given specific use in a medical device. The medical device manufacturer using OTS Software generally gives up software life cycle control, but still bears the responsibility for the continued safe and effective performance of the medical device.

This guidance document was developed to address the many questions asked by medical device manufacturers regarding what they need to provide in a premarket submission to the FDA when they use OTS Software. The specific response to these questions depends on the medical device in question and the impact on patient, operator, or bystander safety if the OTS Software fails. Thus, the answer to the question, “What do I need to document?” may differ and is based on the risk analysis that is an integral part of designing a medical device. The detail of documentation to be provided to FDA and the level of life cycle control necessary for the medical device manufacturer increase as severity of the hazards to patients, operators, or bystanders from OTS Software failure increases.

This document lays out in broad terms how the medical device manufacturer can consider what is necessary to document for submission to the Agency. A basic set of need-to-document items is recommended for all OTS Software, and a detailed discussion is provided on additional (special) needs and responsibilities of the manufacturer when the severity of the hazards from OTS Software failure become more significant.
For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.\(^1\) For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.\(^2\)

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

II. Scope

The purpose of this document is to describe the information that generally should be provided in a medical device application involving OTS Software. This information is in addition to the documentation described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.\(^3\) Many of the principles outlined herein may also be helpful to device manufacturers in establishing design controls and validation plans for use of OTS Software in their devices. This guidance discusses key elements reviewers should look for in the submission, thereby providing a common baseline from which both manufacturers and reviewers can operate. This should improve predictability of Agency interaction with sponsors regarding applications involving OTS Software.

The guidance provided in this document reflects a safety-based approach to risk management and is designed to be consistent with international standards on risk management. Existing international standards indicate that the estimation of risk should be considered as the product of the severity of harm and the probability of occurrence of harm. Probabilities of occurrence are calculated based on clinical and engineering considerations. On the clinical side, manufacturers use patient populations, user skill sets, labeling, and risk benefit analysis to calculate risk and acceptable risk levels. On the software engineering side, probabilities of occurrence would normally be based on software failure rates. However, software failures are systematic in nature and therefore their probability of occurrence can not be determined using traditional statistical methods.

Because the risk estimates for hazards related to software cannot easily be estimated based on software failure rates, CDRH has concluded that engineering risk management for medical device software should focus on the severity of the harm that could result from the software failure. ‘Hazard Analysis’ is defined as the identification of hazards and their initiating

\(^1\) Available at [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).


causes. Based on the definition of ‘Risk Analysis’, hazard analysis is actually a subset of risk analysis; because risk analysis for software cannot be based on probability of occurrence, the actual function of risk analysis for software can then be reduced to a hazard analysis function. Technically speaking, the use of either term risk or hazard analysis is appropriate. However, CDRH has chosen to use the term hazard analysis to reinforce the concept that calculating risk based on software failure rates is generally not justified, and that it is more appropriate to manage software safety risk based on the severity of harm rather than the software failure rates.

III. Definitions

Following a safety-based approach to risk analysis, we define:

Hazard – A possible source of danger or a condition that could result in human injury.

Hazard Analysis – Identification of hazards and their initiating causes.

Hazard Mitigation – Reduction in the severity of the hazard, the likelihood of the occurrence, or both.

Major Level of Concern – The Level of Concern is major if operation of the software associated with device function directly affects the patient, operator, and/or bystander so that failures or latent flaws could result in death or serious injury to the patient, operator, and/or bystander, or if it indirectly affects the patient, operator, and/or bystander (e.g., through the action of care provider) such that incorrect or delayed information could result in death or serious injury to the patient, operator, and/or bystander.

Minor Level of Concern – The Level of Concern is minor if failures or latent design flaws would not be expected to result in any injury to the patient, operator, and/or bystander.

Moderate Level of Concern – The Level of Concern is moderate if the operation of the software associated with device function directly affects the patient, operator, and/or bystander so that failures or latent design flaws could result in non-serious injury to the patient, operator, and/or bystander, or if it indirectly affects the patient, operator, and/or bystander (e.g., through the action of the care provider) where incorrect or delayed information could result in non-serious injury of the patient, operator, and/or bystander.

Off-the-Shelf Software (OTS Software) – A generally available software component, used by a medical device manufacturer for which the manufacturer cannot claim complete software life cycle control.

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4 ISO 14971 Medical devices — Application of risk management to medical devices.
**Risk Analysis** – Investigation of available information to identify hazards and to estimate risks.\(^5\)

**Risk Control** – The process through which decisions are reached and implemented for reducing risks to, or maintaining risks within, specified limits.\(^6\)

**Safety** – In the regulation of medical devices, safety means that the probable benefits to health for its intended use when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. In this guidance we will use the words “safety and effectiveness” to remind ourselves that safety is only meaningful in the context of the benefit-risk considerations and the labeling.

**Serious Injury** – As adopted from the Medical Device Reporting (MDR) regulation in 21 CFR 803.3(w), means an injury or illness that:

1. Is life threatening,
2. Results in permanent impairment of a body function or permanent damage to a body structure, or
3. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**Permanent** – For the purpose of this subpart, permanent means irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

Other software terminology used in this document is defined in FDA's [Glossary of Computer System Software Development Terminology].\(^7\)

**IV. OTS Software Decision Schematic**

The content of the application supporting use of OTS Software in a medical device depends on the results of the hazard analysis. Figure 1 provides a schematic of the decision process and a table of contents for Section V of this guidance document.

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\(^5\) ISO 14971 *Medical devices — Application of risk management to medical devices.*

\(^6\) ISO 14971 *Medical devices — Application of risk management to medical devices.*

Figure 1. OTS Software Decision Schematic

Does the device include OTS Software?
(See definition, Section III)

Yes →

Provide Basic Documentation
(See Section V.A)

Perform Device & OTS Software Hazard Analysis
Does the OTS Software present a Minor Level of Concern (LOC)?
(See Section V.B)

Yes →

Done

Minor LOC

No →

Hazard Mitigation
(See Section V.C)

Describe and Justify Residual Risk
(See Section V.D)

Does the OTS Software (after hazard mitigation) represent a Major Level of Concern?

No →

Minor or Moderate LOC

Yes →

Major LOC

Provide OTS Software Special Documentation
(See Section V.E)

Done
Table 1 summarizes the recommended contents for an OTS Software submission based on Figure 1.

**Table 1. Documentation Summary from Figure 1.**

<table>
<thead>
<tr>
<th>Minor Level of Concern before mitigations</th>
<th>Minor Level of Concern after mitigations</th>
<th>Moderate Level of Concern</th>
<th>Major Level of Concern after mitigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Analysis</td>
<td>Hazard Analysis</td>
<td>Hazard Analysis</td>
<td>Hazard Analysis</td>
</tr>
<tr>
<td>Basic Documentation</td>
<td>Basic Documentation</td>
<td>Basic Documentation</td>
<td>Basic Documentation</td>
</tr>
<tr>
<td>Hazard Mitigations</td>
<td>Hazard Mitigations</td>
<td>Describe and Justify Residual Risk</td>
<td>Describe and Justify Residual Risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Special Documentation</td>
<td></td>
</tr>
</tbody>
</table>

**V. OTS Software Use**

**A. Basic Documentation for OTS Software**

The OTS Software Basic Documentation is intended to answer the following questions:

1. **What is it?**

For each component of OTS Software used, the following should be specified:

- Title and Manufacturer of the OTS Software.
- Version Level, Release Date, Patch Number, and Upgrade Designation, as appropriate.
- Any OTS Software documentation that will be provided to the end user.
- Why is this OTS Software appropriate for this medical device?
- What are the expected design limitations of the OTS Software?

**Note:** The medical device manufacturer should only use the OTS Software as specified in an appropriate document, i.e., design record. If the version of the OTS Software changes, the appropriate document should be updated to reflect the change.

2. **What are the Computer System Specifications for the OTS Software?**
For what configuration will the OTS Software be validated? The following should be specified:

- Hardware specifications: processor (manufacturer, speed, and features), RAM (memory size), hard disk size, other storage, communications, display, etc.
- Software specifications: operating system, drivers, utilities, etc. The software requirements specification (SRS) listing for each item should contain the name (e.g., Windows 10, Excel, Sun OS, etc.), specific version levels (e.g., 4.1, 5.0, etc.) and a complete list of any patches that have been provided by the OTS Software manufacturer.

3. **How will you assure appropriate actions are taken by the End User?**

   - What aspects of the OTS Software and system can (and/or must) be installed/configured?
   - What steps are permitted (or must be taken) to install and/or configure the product?
   - How often will the configuration need to be changed?
   - What education and training are suggested or required for the user of the OTS Software?
   - What measures have been designed into the medical device to prevent the operation of any non-specified OTS Software, e.g., word processors, games? Operation of non-specified OTS Software may be prevented by system design, preventive measures, or labeling. Introduction may be prevented by disabling input (USB, CD, modems).

4. **What does the OTS Software do?**

What function does the OTS Software provide in this device? This is equivalent to the software requirements in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for this OTS Software. The following should be specified:

- What is the OTS Software intended to do? The sponsor’s design documentation should specify exactly which OTS components will be included in the design of the medical device and to what extent OTS Software is involved in error control and messaging in device error control.
- What are the links with other software including software outside the medical device (not reviewed as part of this or another application)? The links to outside software should be completely defined for each medical device/module. The design documentation should include a complete description of the linkage between the medical device software and any outside software (e.g., networks).

5. **How do you know it works?**

---

Based on the Level of Concern:

- Describe testing, verification, and validation of the OTS Software and ensure it is appropriate for the device hazards associated with the OTS Software. (See Note 1.)
- Provide the results of the testing. (See Note 2.)
- Is there a current list of OTS Software problems (bugs) and access to updates?

Note 1: FDA recommends that software test, verification, and validation plans identify the exact OTS Software (title and version) that is to be used. When the software is tested it should be integrated and tested using the specific OTS Software that will be delivered to the user.

Note 2: If the manufacturer allows the use of the medical device with different versions of OTS Software, then the manufacturer should validate the medical device for each OTS Software version.

6. How will you keep track of (control) the OTS Software?

An appropriate plan should answer the following questions:

- What measures have been designed into the medical device to prevent the introduction of incorrect versions? On startup, ideally, the medical device should check to verify that all software is the correct title, version level, and configuration. If the correct software is not loaded, the medical device should warn the operator and shut down to a safe state.
- How will you maintain the OTS Software configuration?
- Where and how will you store the OTS Software?
- How will you ensure proper installation of the OTS Software?
- How will you ensure proper maintenance and life cycle support for the OTS Software?

B. OTS Software Hazard Analysis

A comprehensive risk management approach includes hazard analysis and mitigation that continues iteratively throughout the life of the product. The manufacturer is expected to perform an OTS Software hazard analysis as a part of a medical device (system) hazard analysis.

OTS Software failure, malfunction, or misuse may present a hazard to the patient, operators, or bystanders. Figure 2 summarizes the typical hazard management and mitigation process that would include a hazard analysis of the OTS Software component.

The submission should include the following information to document the OTS Software hazard analysis:
Contains Nonbinding Recommendations

- A list of all potential hazards identified.
- The estimated severity of each identified hazard.
- A list of all potential causes of each identified hazard.

**Note:** A tabular format of the OTS Software hazard analysis or a tabular summary will facilitate review. The hazard analysis for OTS Software may be included in the overall device hazard analysis provided adequate documentation is provided.

If the device with the OTS Software represents a Minor Level of Concern, then the Level of Concern for the OTS Software can be no greater. The hazard analysis for the OTS Software in such a device may simply document the Minor Level of Concern of the device.

Where failure, malfunction, or misuse of the OTS Software poses no possibility of injury to the patient, operators, or bystanders, then the OTS Software is said to present a Minor Level of Concern, and the fulfillment of the Basic Documentation (see Section V.A) will be considered sufficient.

**C. OTS Software Hazard Mitigation**

Hazard mitigation activities may seek to reduce the severity of the hazard, the likelihood of the occurrence, or both. Hazard mitigation interventions may be considered in three categories with the following order of precedence:

- Design (or redesign)
- Protective measures (passive measures)
- Warning the user (labeling)
Figure 2. Typical Hazard Analysis and Mitigation

1. Identify all potential hazards 1...X
2. Estimate severity of hazard n
3. Identify all causes 1...x of hazard n (including OTS software)
4. Mitigate cause(s) of hazard n by
5. Mitigate hazard by:
   - Inherent safe design
   - Protective measures
   - User information and training
6. Evaluate results of mitigation measures
7. Determine if new hazards have been introduced
8. Has the severity or the likelihood of the hazard occurrence been reduced to an acceptable level?
   - No
   - Yes

Hazard Mitigation Complete
These approaches may involve hardware and/or software. These three mitigation approaches are by no means mutually exclusive and may be used concurrently. The most desirable approach is to design in effective controls, i.e., eliminate the need for a hazardous operation or component. Protective measures are considered passive (from the user’s standpoint) since they do not require any action on the part of the user. The least effective approaches depend on some action (or lack of action) on the part of the medical device user.

The submission should include the following information to document the OTS Software hazard mitigation:

1. A list of all identified medical device hazards associated with the OTS Software;
2. The steps taken to mitigate each hazard; and
3. The residual risk.

Note: A tabular format of the risk management or a tabular summary will facilitate review. These results will typically be included as a part of the overall medical device hazard analysis and mitigation plan.

One example of a comprehensive approach to injury prevention in public health was developed around ten “countermeasures.” Table 2 (see next page) illustrates a generic approach to the hazard mitigation, in this case, to preventing injury-related energy release to patients, operators, or bystanders.

With implementation of each hazard mitigation, the residual risk is assessed as well as assessment of any new hazards that may be introduced.

Acceptable levels of residual risk, based on the severity or the likelihood of the residual risk occurring, will depend on the intended use of the medical device and the function performed by the software. In the case of diagnostic tests, injury includes results that can lead to unnecessary invasive diagnostic testing (e.g., biopsy) or withholding or delaying important diagnostic or therapeutic procedures.

The sponsor will need to describe and justify the residual risk (Section V.D) for Moderate or Major Levels of Concern. Where failure, malfunction, or misuse of the OTS Software is likely to result in death or serious injury to the patient, operators, or bystanders, then the OTS Software is said to present a Major Level of Concern. If the residual risk from the OTS Software presents a Major Level of Concern, the sponsor will need to fulfill Special Documentation (Section V.E).

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Table 2. Injury Reduction Countermeasures

| 1. Prevent accumulation of the energy. |
| 2. Reduce the amount of the energy delivered. |
| 3. Prevent inappropriate release of the energy. |
| 4. Modify the release of the energy. |
| 5. Separate the patient from the energy in time and space. |
| 6. Provide physical barriers between the energy and the patient. |
| 7. Change the surfaces or basic structures at the interface. |
| 8. Reduce likelihood of misapplication or Increase resistance of the patient. |
| 10. Improve medical care and rehabilitation after the injury. |

D. Describe and Justify Residual Risk

The sponsor should provide a detailed (complete) discussion of the risk that remains.

The risk related to the use of OTS Software should be considered in relation to the risk of the alternatives, e.g., custom developed software. Any experience (data) with the use of the OTS Software in this or a related application should be presented by the sponsor and will be considered by the reviewers. Whether the residual risk is acceptable depends on the specific medical device application.

E. Special Documentation for OTS Software

To fulfill Special Documentation for OTS Software of a Major Level of Concern, the medical device manufacturer is expected to:

1. Provide assurance to FDA that the product development methodologies used by the OTS Software developer are appropriate and sufficient for the intended use of the OTS Software within the specific medical device. FDA recommends this include an audit of the OTS Software developer’s design and development methodologies used in the construction of the OTS Software. This audit should thoroughly assess the development and qualification documentation generated for the OTS Software (see Note below).

   **Note:** If such an audit is not possible and after hazard mitigation, the OTS Software still represents a Major Level of Concern, the use of such OTS Software may not be appropriate for the intended medical device application.

2. Demonstrate that the procedures and results of the verification and validation activities performed for the OTS Software are appropriate and sufficient for the safety and effectiveness requirements of the medical device. Verification and validation activities include not only those performed by the OTS Software developer, but also
include those performed by the medical device manufacturer when qualifying the OTS Software for its use in the specific medical device.

3. Demonstrate the existence of appropriate mechanisms for assuring the continued maintenance and support of the OTS Software should the original OTS Software developer terminate their support.

VI. OTS Software Used in Marketing Applications

A. Examples

Examples of medical devices using OTS Software are described in this section. These examples illustrate the reasoning that leads to defining the Level of Concern for a medical device and thus the kinds of development processes that should be used and the information to be provided in a regulatory submission.

(1) Corneal Topographer

Minor Level of Concern medical device (see Section V.A).

**Intended Use:** A corneal topographer provides images of the abnormalities in the curvature of the cornea, the simplest being astigmatism.

**Description:** A corneal topographer consists of a hollow cone that the patient looks into from the base looking towards the interior of the point (like looking into the big end of a megaphone with one eye). The inside of the cone is white with black concentric circles. The concentric circles reflect off the eye and are imaged by a camera with a computer controlled lens situated at the point of the cone looking at the patient’s eye. The shapes of the reflections of the concentric circles are used to develop a topographic map of the cornea curvature that is printed out.

**OTS Software:** An OTS operating system such as Windows is commonly used to interface the user, the microcomputer hardware platform, the corneal topographer, data storage, and output devices.

**OTS Software Level of Concern:** A corneal topographer represents no threat of direct harm to the patient. The risk of indirect harm from a misdiagnosis relating to medical device malfunction is small since the worst case is an incorrect image that is considered correct. The OTS Software in this medical device thus represents a Minor Level of Concern (see Section V.B) and should satisfy Basic Documentation (see Section V.A).

(2) Perineometer

Minor Level of Concern medical device (see Section V.A).

**Intended Use:** Perineometers are used to provide feedback to a patient performing muscle strengthening exercises (Kegel exercises) for the treatment of certain types of urinary incontinence.
Description: There are two types of perineometers: those that measure pressure, and those that measure electrical activity (EMG) from muscles. Each device consists of a probe that is placed into either the vagina or the rectum, and a monitoring unit. The pressure devices use an air-filled probe connected to the monitoring unit by a piece of plastic tubing. When the patient performs the exercise, the probe is compressed, and the monitoring unit reports the change in pressure. The electrical devices use an electrode to measure the electrical activity of the target muscles during the exercises, and this information is reported by the monitoring unit.

OTS Software: An OTS operating system, such as DOS or Windows, may be used to record and display the data collected by the monitoring unit.

OTS Software Level of Concern: Perineometers represent no threat of direct injury to the patient, since no energy is applied by the medical device to the patient. The risk of indirect injury due to inaccurate feedback during the exercise session is expected to be small, as these medical devices are only used as an adjunct to exercise therapy, and they are used under clinical supervision. The OTS Software in this medical device thus represents a Minor Level of Concern (see Section V.B) and should satisfy the Basic Documentation (see Section V.A).

(3) Implantable Medical Device Programmers

Describe and Justify Residual Risk (see Section V.E).

Intended Use: An implantable medical device programmer provides interface and two-way communication with an implantable cardioverter-defibrillator (ICD) or cardiac pacemaker.

Description: An implantable medical device programmer consists of an electromagnetic programming head that is placed over the implanted device and provides through-the-skin communication with the implanted device, the personal computer (PC) interface, and the PC hardware and software. The programmer permits the physician-user to:

- Query the implant for performance history (device and patient), and, in some systems, for print-out of the recorded electrograms;
- Set the adjustable (programmable) characteristics of the implant;
- Provide the induced shock for system initialization and diagnostic purposes; and
- Verify implant operating characteristics and status (including battery) via signals from the implant.

OTS Software: An OTS operating system such as DOS or Windows is used to provide a user interface (sometimes graphical), interface to the PC (hardware platform), and interface with data storage, and output devices.

OTS Software Level of Concern: The on-board software for the implant satisfies the definition of Major Level of Concern software (life supporting/life sustaining) and would need to satisfy the Special Documentation (see Section V.E). Whether the device programmer can be considered of lesser Level of Concern depends primarily on the
protection designed into the implant or the programmer. Steps taken to mitigate the risk might include:

- Design of the implant to minimize the possibility of misprogramming to inappropriate operational states;
- Design of the programmer interface to minimize the chance of miscommunication, including hardening of the hardware against electromagnetic interference (EMI);
- Limiting the part of the OTS Software that is utilized in the programming application;
- Protecting the PC from use for other applications, including consideration of the following:
  - Software design features to protect against adding unwanted software, modification, or system use; and
  - Hardware design features to protect against unwanted system use.

Other points that might be offered to support use of OTS Software in the programmer might include:

1. Documented experience (data) with use of the OTS Software in this application.
   - What was the system in place to detect and report problems?
   - What is the rate of problems reported compared to other (perhaps non-OTS Software) systems?

2. Documented experience with the OTS Software in other relevant applications.
   - What are the reported problems (bug list) and how many are relevant to this application?
   - Has there been difficulty in developing work-arounds for the problems relevant to this application?

The review team must decide whether the overall programmer system as implemented satisfies the necessary system safety and effectiveness (see Section V.E).

**B. 510(k) Issues with OTS Software**

The conditions under which a new or changed medical device including OTS Software will require a new 510(k) are the same as for a device not involving OTS Software. These conditions are given in the CDRH’s guidances, “Deciding When to Submit a 510(k) for a Change to an Existing Device,”\(^{10}\) and “Deciding When to Submit a 510(k) for a Software Change to an Existing Device.”\(^{11}\)

(1) OTS Software Changes Requiring a 510(k)

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For medical devices where the OTS Software represents a Minor Level of Concern, OTS Software changes would not typically require a new 510(k). However, the manufacturer is responsible for validating the change.

For other medical devices, the decision as to whether a new 510(k) is required depends on the intended use of the device; the function of the OTS Software; and to what extent the risks due to OTS Software have been mitigated (see guidances on when to submit a 510(k) for a modification\(^\text{12,13}\)).

**C. Investigational Device Exemption Issues with OTS Software**

The requirements for an investigational device exemption (IDE) are the same whether or not the medical device contains OTS Software. The OTS Software may be a component of a medical device or the OTS Software may be the entire medical device, e.g., diagnostic software. The conditions that would require submission of an IDE are specified in section 21 CFR 812 and generally include changes that would affect the patient population for which the medical device is intended; conditions of use of the device (including those recommended or suggested in the labeling or advertising; the probable benefit from the use of the device weighed against any probable injury or illness from such use); or the reliability of the medical device.

Some specific issues related to OTS Software might include initial (beta) testing of an OTS Software medical device in clinical studies. Such a study must comply with applicable IDE requirements.\(^\text{14}\) For non-significant risk medical devices, that includes approval by an institutional review board (IRB) and patient informed consent. For significant risk studies, the initial user testing (beta testing) protocol would be included in an IDE submission. For example, beta testing of radiation treatment planning software, including any OTS Software modules, would be conducted under a full IDE with FDA approval as a prerequisite. See the guidance on “Significant Risk and Nonsignificant Risk Medical Device Studies”\(^\text{15}\)” for more information.

**D. Exemption of Certain Diagnostic Devices**

If the product incorporating the OTS Software is a diagnostic medical device, it may be exempted from IDE requirements, if it meets the criteria in section 21 CFR 812.2(c)(3). For example, clinical (beta) testing of a noninvasive diagnostic device that does not require significant risk invasive sampling procedure and that does not introduce energy into the


\(^{13}\) Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

\(^{14}\) See 21 CFR 812.

body, is exempted from IRB approval, patient informed consent, and other IDE requirements, if a medically established diagnostic product or procedure is used to confirm the diagnosis.

E. Premarket Approval Issues with OTS Software

The criteria and requirements for premarket approval (PMA) applications are in section 21 CFR 814. When a manufacturer submits a PMA submission for a medical device, there must be valid scientific evidence (including clinical evidence, if needed) to support a reasonable assurance of safety and effectiveness of the device.\(^{16}\)

The OTS Software used in a medical device is evaluated in the context of the overall medical device. The extent to which the medical device manufacturer ensures that the OTS Software was developed using appropriate life cycle control depends upon the overall risk of the medical device, the role of the OTS Software, and the Level of Concern associated with possible failures of the OTS Software component.

For example, a commercially available neural network, used by a medical device manufacturer for pattern recognition, would require extensive validation if used in a Pap smear screening device, in computer-assisted radiology, or for computer-assisted analysis of ECG waveforms. The same neural network, used for less critical computer-assisted analysis of EEG waveforms, might require less rigorous software documentation. Likewise, a commercially available personal computer operating system with graphical user interface, would require extensive documentation and evidence of validation when intended for use in a cardiac pacemaker programmer. Less documentation and verification of the OTS operating system would be required for programming an artificial ear.

F. Artificial Intelligence

OTS knowledge-based software (for example, artificial intelligence, expert systems, and neural net software) are being developed for a number of medical applications. A typical system accepts clinical findings (sometimes including imaging data) and generates probabilities of disease states and/or recommendations for subsequent data gathering or treatment. The clinician may order a surgical biopsy or other invasive tests or initiate therapy based on the system output. Such systems should be tested and reviewed in a manner consistent with both their safety and effectiveness of their direct effects (recommendations) and indirect effects (missed appropriate diagnostic testing and treatment).

G. Product Labeling

FDA recommends that the user’s manual specify the version(s) of the OTS Software that can be used with the medical device. Such specification would not be needed for embedded software (i.e., the user does not select the OTS Software and cannot change the software provided by the medical device manufacturer).

\(^{16}\) See 21 CFR 860.7.
The user’s manual should contain appropriate warnings to the user indicating that the use of any software other than those specified will violate the safety, effectiveness, and design controls of this medical device and that such use may result in an increased risk to users and patients. Further description of what comprises a warning and how to write it are included in the Device Labeling Guidance\(^\text{17}\) and the guidance on Labeling – Regulatory Requirements for Medical Devices.\(^\text{18}\)

When OTS medical device software is delivered on a magnetic / user installable medium, the package should include labeling that indicates the minimum hardware platforms on which the software is validated to run (processor, memory, disk, interface, etc.). The appropriate testing for the user to assure proper installation should also be described in the labeling.

If the hardware on which the OTS Software runs is a stand-alone computer and the user is not “locked out” by hardware or software system features, then the user should be warned against installing any other software (utilities or applications programs) on the computer.

**VII. Appendix**

The purpose of these Appendices is to provide background and comment on various OTS Software. Based on the Level of Concern, device manufacturers should either use or not use Commercial Off-the-shelf Software (COTS).

**A. Operating Systems**

The operating system software is the primary software program that manages the basic functions of the computer and its associated hardware, including peripherals. The operating system provides a basic user interface, is responsible for managing applications programs and tasks, controlling memory allocation and data storage devices, and providing input/output for the computer, as well as any additional peripheral devices that are present.

“Open” hardware (mass market) architecture computers vary widely in architectural and organizational characteristics such as timing, addressing, and processing. Operating systems and application software executing on these platforms should be “robust” enough to perform appropriately in this environment.

OTS driver software packages provide interface functions between the CPU, operating system, and the input/output peripheral. However, the performance and functionality of the OTS driver software may be affected by the overall system configuration and the OTS hardware. In general, OTS driver software packages can be classified into the following input/output interface types: serial, parallel, video signal, telemetry, LAN, and internal bus.


In most cases, a particular software driver derives from a particular interface protocol and contains the data signals, control signals, and timing signals for proper operation.

Since tests for most input/output interface/bus configurations require the particular bus analysis or logic analysis, scope, and knowledge of the particular interface protocol, the validation process for the OTS driver software package should be part of the system interface validation process for higher levels of concern. This includes the verification of the data values in both directions for the data signals; various mode settings for the control signals in both directions (if applicable); and the input/output interrupt and timing functions of the driver with the CPU and operating system.

B. Utilities and Drivers

The purpose of this Appendix is to provide general recommendations and background for the use of OTS utility and driver software packages in the medical device validation process.

Utility software is generally designed to work with a specific operating system. Unlike applications software, utility software is intended to supplant or enhance functions typically performed by the operating system. Examples of utility programs are memory managers, file managers, and virus checkers. Networking software can also be considered as utility software in that it allows multiple computers to access the same resources. Operating systems can also be designed to support or enable network operations without any additional utility software.

OTS operating systems are commonly considered for incorporation into medical devices as the use of general-purpose computer hardware becomes more prevalent. The use of OTS operating system software allows device manufacturers to concentrate on the application software needed to run device-specific functions. However, an OTS operating system software is intended for general-purpose computing and may not be appropriate for a given specific use in a medical device. Developers of OTS operating systems typically design their systems for general-purpose business or consumer computing environments and tasks where software failures and errors are more accepted. This acceptability of errors in the general-purpose computing environment may make the OTS operating system software inappropriate for less error-tolerant environments or applications.

The incorporation of OTS operating system software may also introduce unnecessary functions and complexity into a medical device. General-purpose functional requirements typically result in the OTS operating system software being large and unwieldy in the attempt to incorporate more functionality into the operating system. This excess functionality is typically never used for specific medical device applications and increases the likelihood that errors may be introduced into the operating system. The basic functions of an OTS operating systems used for medical device applications are typically the graphical user interface environment and the hardware interface functions. There are a number of operating systems used for timing- or resource-critical applications that provide the basic functionality needed to support user and hardware interfaces, but do not have many of the disadvantages of general-purpose business or consumer operating systems.
OTS utility software packages can perform the following functions: math functions (fast Fourier transform, sin, cos); display functions (graphic); management functions (copy, delete, store various computer data/files); and the data manipulation function (transfer from one Boolean type or both). The validation for these types of the software should be appropriate to the Level of Concern.

C. Local Area Networks (LANs)

The purpose of this Appendix is to provide general recommendations and background for the network aspects of OTS Software use. Medical devices, particularly multi-parameter patient monitors and imaging systems, are increasingly networked for clinical work groups, centralized monitoring, and storage of patient medical data and records. LANs and other networks support more and more communication and sharing of images, measurement data, audio, video, graphics, text, etc. This heterogeneous media environment comes at a cost of more processing power, higher bandwidth or network speed, sophisticated object-relational databases, and security and access considerations.

The evaluation of networked medical devices begins with a definition of the technical requirements of the network application and the understanding of those requirements.

(1) Requirements Analysis

1. Speed – The response time required for safe and effective operation determines the LAN data rate (bandwidth) for the medical device system. The CPU processing power and clock speed required at device monitors, workstations, and client machines should be appropriate so that bottlenecks do not occur.

2. LAN Architecture – The size of the LAN (the number of user nodes) and the topology of the LAN should be specified.
   - Discuss to what extent the LAN needs to be fault tolerant, e.g., when a workstation fails?
   - Discuss to what extent the LAN needs to be scaleable, i.e., can new user nodes be added without degrading system performance?
   - Discuss to what extent the main device software needs to be computationally self-sufficient or distributed.

3. Network Operating System (NOS) – Whether OTS or proprietary, this selection should consider the trade-off between robustness and flexibility.

4. Data Integrity – One of the most important issues for any medical device operating in a network is data integrity. The manufacturer should ensure that the network system software and hardware incorporate error checking, handling, and correction measures commensurate with the Level of Concern of the device.
Contains Nonbinding Recommendations

- Transmission of data packets and files should include error detection and correction. Error detection methods include parity, checksum, and cyclic redundancy check (CRC).
- Transaction rollback after non-committed changes or network failure, supports data integrity in medical device LANs.
- Critical data and files may be stored in duplicate at separate locations.


The above five items are not independent. Decisions made in one item area may affect the performance of the LAN in another area.

(2) Implementation

The speed required by the medical device system dictates the hardware selection, the network interface cards and transmissions protocols. For example, if the conventional Ethernet protocol (maximum transmission speed of 10 Mbps) is too slow for the intended application, then a different transmission protocol will be needed.

Simplicity of the LAN architecture versus fault tolerance is a trade-off that may arise in the implementation of the networked medical device systems. The LAN could be implemented as a linear bus network (perhaps the simplest scheme), but if any connecting link on the bus fails, the whole network can fail. A star topology with redundant centralized hub is an example of a more complex but more robust network structure.

Segmentation of high bandwidth applications may be employed to improve LAN performance. Limiting the data traffic to data intensive clusters reduces traffic throughout the overall LAN.

D. Device Master Files

Much of the information regarding development and validation of OTS Software may not be readily available to the medical device manufacturer who wishes to use the OTS Software as a device component. Commercial OTS Software vendors who wish to make their OTS Software available for use in medical devices, but do not want to share the confidential and/or proprietary details of their software development and validation with customers (medical device manufacturers), may direct the information in a device master file to the FDA. Additional information on Device Master Files can be found on the FDA website: https://www.fda.gov/medical-devices/premarket-approval-pma/master-files.

E. Maintenance and Obsolescence

This Appendix addresses relevant maintainability issues with regard to OTS Software in medical devices.
Maintenance activities are generally considered to begin subsequent to the establishment and distribution of a medical device product baseline. The distinction between maintenance and product development is an important one. Product development design activities generally lead to a system structure of highly integrated components and logic. Maintenance activities introduce changes into this structure that may lead to a loss in the integrity of the structure. Structure integrity may be affected through changes due to new design requirements, corrections, or environmental adaptations. These types of changes may impact the integrity of the structure organization, architecture, logic, integration, or any combination of these characteristics. Maintenance of products with OTS Software components may be particularly problematic for reasons discussed in the main body of this document, i.e., the sponsor does not have control of the OTS Software component life cycle process.

In particular, this section identifies general safety and effectiveness, design, verification/validation, change, installation, and decommissioning concerns. These concerns may be applied to all regulated medical device software and stand-alone medical software devices. The appropriate evaluation will depend on the Level of Concern.

Assumptions for this Section include:

- Manufacturer Good Software Development Practices (GSDP) and Good Corrective Action Practices (GCAP) are in place.
- A product baseline exists.
- A new product baseline based on a prior product baseline is under CDRH review.

Each concern below corresponds to a product development life cycle phase. The concerns identify fundamental maintenance concerns relevant to medical devices that include software. Guidance in the main body of this document provides the procedural foundation for concerns in this Section.

(1) Safety

Introduction of new or modified OTS components to a product baseline may impact the safety of the product. Therefore a safety impact assessment of the medical device should be performed and associated hazards documented in a Failure Modes and Effects Analysis (FMEA) table. Each hazard’s consequence should be provided and expressed qualitatively; e.g., major, moderate, or minor. Traceability between these identified hazards, their design requirements, and test reports should be provided.

Analysis should include the review of release bulletins (known error reports), user manuals, specifications, patches, and literature and internet searches for other user’s experience with this OTS Software.

The submission should answer the following questions:

- Has a FMEA with traceability to requirements and test reports been provided?
- Are safety functions isolated from new OTS component(s)?
- Does the new OTS component affect system safety integrity?
What new human factors conditions are introduced with new OTS components?

(2) **Design**

Introduction of new or modified OTS Software components to a product baseline may impact the original design of the product. This impact may result from necessary changes to the product structure organization, architecture, logic, integration, or a combination of these characteristics.

Problems attributable to structural changes include:

- New system resource requirements, such as shared and/or fixed memory;
- New timing considerations;
- New memory organization (e.g., 16 bit to 32 bit to 64 bit words), partitioning;
- New human factor issues;
- New data integrity issues; and
- New software required to create the final code (build tools).

Consequently the submission should answer the following questions:

- How will the new OTS Software component(s) change the performance characteristics?
- How will the new OTS Software component(s) change the operational environment?
- Is data integrity preserved?

(3) **Verification and Validation**

As in the establishment of a product baseline, verification and validation (V&V) activities should occur when maintenance changes are made to a product baseline. Analysis of these changes directs necessary V&V activities. New OTS Software components in a product baseline introduce unknown logic paths and complexities into the product. “Black-box” testing of OTS Software components may allow some validation claims to be made. However, the unknown logic paths and complexities of OTS Software components make it important to know that design structure or logic elsewhere in the system is not impacted. This means a full system regression test should be performed. Results of these validation activities should be documented.

The submission should answer the following questions:

- Do test reports provide objective evidence that identified OTS Software component hazards have been addressed?
- Do test reports provide objective evidence that all identified system hazards have been addressed?
- Has a system regression test been performed?

(4) **Installation**
Changes in a product baseline structure resulting from the integration of new OTS Software components may impact installation requirements. This impact can range from minor documentation changes to field upgrades. The reviewer should ascertain the impact of OTS Software component changes on fielded products.

The submission should answer the following question: What is the impact of new OTS Software components on fielded medical device products?

For example: Do new OTS Software components correctly operate within the specifications of medical devices currently fielded?

**(5) Obsolescence**

Rapid technology changes, economics, and market demand are shrinking product life spans. A direct consequence of these phenomena is that an OTS Software component today may not exist two years from now. Short life spans are a particular characteristic of software because it is relatively easy to change. Obsolescence of OTS Software components can have significant impact on regulated products because the device manufacturer may lose the ability to properly support fielded products. The sponsor needs to support fielded medical device products with OTS Software components.

The submission should answer the following questions:

- Will the old OTS Software component still be available for fielded medical devices?
- Is there a retirement plan for OTS Software components to be replaced/eliminated?
- Do new OTS Software component(s) replace fielded components?

**(6) Change Control**

The submission must identify the product to be considered. Therefore, the product configuration provided should specify:

- Hardware platform (e.g. microprocessor, minimum memory required, addressable word size);
- Software platform (e.g. operating system, communications, databases, necessary utilities, etc.);
- OTS component(s) other than (B) above (see basic requirements in the main body of this document); and
- Internally developed application(s).
Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2014-D-0798. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) recognizes that the progression to digital health offers the potential for better, more efficient patient care and improved health outcomes. To achieve this goal requires that many medical devices be interoperable with other types of medical devices and with various types of health information technology. The foundation for such inter-communication is hardware and software, typically referred to as medical device data systems (MDDS) that transfer, store, convert formats, and display medical device data or medical imaging data.

On February 15, 2011, the FDA issued a regulation down-classifying MDDS from Class III (high-risk) to Class I (low-risk) (“MDDS regulation”). Since down-classifying MDDS, the FDA has gained additional experience with these types of technologies, and has determined that these devices pose a low risk to the public. On February 9, 2015, the FDA issued a guidance document to inform manufacturers, distributors, and other entities that the Agency does not intend to enforce compliance with the regulatory controls that apply to MDDS, medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health.

Since the issuance of the guidance document in 2015, section 3060(a) of the 21st Century Cures Act (Cures Act) amended section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) on December 13, 2016, removing certain software functions from the definition

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1 See Medical Devices; Medical Device Data Systems Final Rule (76 FR 8637) (Feb. 15, 2011).
of device in section 201(h) of the FD&C Act. Pursuant to section 520(o)(1)(D) of the FD&C Act, *software functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or medical imaging data, unless the software function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings, are not devices and are not subject to FDA laws and regulations applicable to devices. The definition of MDDS in 21 CFR 880.6310 is currently inconsistent with the definition of device as amended pursuant to the Cures Act. FDA intends to amend the regulation to be consistent with the amended device definition. FDA’s current thinking on the definition of MDDS is reflected in this guidance.

*Hardware products* that are intended to transfer, store, convert formats, and display medical device data and results remain devices under section 201(h) of the FD&C Act. FDA does not intend to enforce compliance with the regulatory controls for such devices, provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data.

The policy described in this guidance document is also consistent with the Agency’s updated guidance entitled “*Policy for Device Software Functions and Mobile Medical Applications,*” originally issued on February 9, 2015, with the title “Mobile Medical Applications.”

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## II. Background

FDA uses the following terms in this guidance:

- **Non-Device-MDDS:** *Software functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or results.

- **Device-MDDS:** *Hardware functions* that are *solely intended* to transfer, store, convert formats, and display medical device data or results.

FDA further defines Non-Device-MDDS and Device-MDDS through the following examples:

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A Non-Device-MDDS is a software function solely intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices, which may or may not be intended for active patient monitoring:

- The electronic transfer or exchange of medical device data. For example, this would include software that collects output from a ventilator about a patient's CO₂ level and transmits the information to a central patient data repository.

- The electronic storage and retrieval of medical device data. For example, software that stores historical blood pressure information for later review by a health care provider.

- The electronic conversion of medical device data from one format to another in accordance with a preset specification. For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed.

- The electronic display of medical device data. For example, software that displays a previously stored electrocardiogram for a particular patient.

Other examples of Non-Device-MDDS include:

- Any assemblage or arrangement of network components that includes specialized software expressly created for a purpose consistent with the intended use in the MDDS regulation.

- Software functions specifically labeled (per 21 CFR Part 801) by the manufacturer as a MDDS, provided such products do not provide additional functionality.

- Custom software that is written by entities other than the original medical device manufacturer (for example, hospitals, third party vendors) that directly connects to a medical device, to obtain medical device information.

- Modified portions of software that are part of an Information Technology (IT) infrastructure created and/or modified (writing and compiling software) for specific MDDS functionality. For example, when modifying software for MDDS functionality, only the modified portion is considered MDDS; the original software is not.

A MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. Software functions intended to generate alarms or alerts or

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3 As noted in the preamble of the MDDS regulation, the word “active” represents “any device that is intended to be relied upon in deciding to take immediate clinical action” (21 CFR 8637 at 8644). FDA further noted that there are existing classifications for patient monitoring devices (See, e.g., 21 CFR Part 880, Subpart C (general hospital and personal use monitoring devices); 21 CFR Part 868, Subpart C (anesthesiology monitoring devices); 21 CFR Part 884, Subpart C (obstetrical and gynecological monitoring devices); and 21 CFR Part 870, Subpart C (cardiovascular monitoring devices)).
prioritize patient-related information on multi-patient displays, which are typically used for active patient monitoring, are considered device software functions because these functions involve analysis or interpretation of laboratory test or other device data and results. As noted above, a Non-Device-MDDS may include software functions that transfer, store, convert formats, or display medical device data that may or may not be intended for active patient monitoring.

Software functions that are device functions intended for active patient monitoring include the following characteristics:

- The clinical context requires a timely response (e.g. in-hospital patient monitoring).
- The clinical condition (disease or diagnosis) requires a timely response (e.g., a monitor that is intended to detect life-threatening arrhythmias, such as ventricular fibrillation, or a device used to actively monitor diabetes for time-sensitive intervention).

Examples of devices that provide active patient monitoring include:

- A nurse telemetry station that receives and displays information from a bedside hospital monitor in an ICU.
- A device that receives and/or displays information, alarms, or alerts from a monitoring device in a home setting and is intended to alert a caregiver to take an immediate clinical action.

Examples of products that transfer, store, convert formats, or display medical device data and are Non-Device-MDDS:

- An application that transmits a child’s temperature to a parent/guardian while the child is in the nurse/health room of a school.
- An application that facilitates the remote display of information from a blood glucose meter, where the user of the meter can independently review their glucose and glucose levels, and which is not intended to be used for taking immediate clinical action. In these cases, remotely displaying information such as the most recent blood glucose value or time-lapse between blood glucose measurements is not considered active patient monitoring.

This guidance also provides the policy for medical image storage and medical image communications devices. These devices are defined as follows:

- A medical image storage device, defined under 21 CFR 892.2010, is a device that provides electronic storage and retrieval functions for medical images.
- A medical image communications device, defined under 21 CFR 892.2020, is a device that provides electronic transfer of medical image data between medical devices.
III. Policy for Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

A. Policy for Non-Device-MDDS

Software functions that meet the definition of Non-Device-MDDS, medical image storage devices, or medical image communications devices are not devices under section 201(h) of the FD&C Act. As such, software functions that are solely intended to transfer, store, convert formats, and display medical device data and results, including medical images, waveforms, signals, or other clinical information, are not devices and thus are not subject to FDA regulatory requirements applicable to devices. However, software functions that analyze or interpret medical device data in addition to transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results remain subject to FDA’s regulatory oversight, unless they meet the criteria outlined in section 520(o)(1)(E) of the FD&C Act.

B. Policy for Device-MDDS

Hardware functions that are intended to transfer, store, convert formats, and display medical device data and results remain devices under section 201(h) of the FD&C Act. FDA does not intend to enforce the requirements under the FD&C Act for hardware products that are considered to be Device-MDDS, medical image storage, or medical image communications devices, provided that the hardware function is limited to assisting the following software functions: electronic transfer, storage, conversion of formats, or display of medical device data. These hardware functions may include the following regulations:

a) MDDS subject to 21 CFR 880.6310,

b) Medical image storage devices subject to 21 CFR 892.2010, and

c) Medical image communications devices subject to 21 CFR 892.2020.

This means that for hardware functions that meet the definitions in the regulations listed above, the FDA does not intend to enforce compliance with the regulatory controls, including registration and listing, premarket review, postmarket reporting, and quality system regulation for manufacturers of these types of devices.

Each Device-MDDS regulation listed above contains an exemption from premarket notification; however, limitations to this exemption identified under 21 CFR 880.9 and 21 CFR 892.9 require a premarket notification in the listed circumstances. Even when exceeding these limitations, FDA does not intend to enforce compliance with the regulatory controls for for hardware functions that meet the definitions identified by the above regulations. For example, to the extent that these limitations apply, FDA does not intend to enforce compliance with regulatory controls for a Device-MDDS that is an in vitro device that is
intended for assessing the risk of cardiovascular diseases (21 CFR 880.9(c)(4)) or for use in diabetes management (21 CFR 880.9(c)(5)).

Specialized medical display hardware devices for digital mammography, radiology, pathology, and ophthalmology (see, for example, 21 CFR 892.2050) and other specialized medical display hardware integral to the safe and effective use of a medical device hardware product (such as integral 3D displays in robotic surgery systems and displays built into ICU bedside monitors) have not been considered MDDS, medical image storage, or medical image communications devices. Such medical display hardware devices and other specialized medical display hardware integral to a medical device are not excluded from the device definition by the Cures Act and are not considered to be Device-MDDS.

In some cases, software functions that transfer, store, convert formats, or display medical device data and results are utilized on hardware that is not intended by the hardware manufacturer for a device function under section 201(h) of the FD&C Act. For example, general-purpose hardware IT infrastructure intended for data transfer (e.g., network router), data storage (e.g., network attached storage (NAS)), conversion of data (e.g., PDF software), and display of data (computer monitor) are not device functions. Such products do not meet the definition of a device in section 201(h) of the FD&C Act for either the software or hardware function and are therefore not regulated as devices.

**C. Multiple Function Device Products that contain Non-Device-MDDS or Device-MDDS**

Consistent with section 520(o)(2) of the FD&C Act, which describes the regulation of a product with multiple functions, including at least one device function and at least one software function that is not a device, FDA does not regulate the Non-Device-MDDS functions contained in a multiple function device product. If a multiple function device product contains Device-MDDS functions, FDA does not, at this time and based our current understanding of the risks of these devices, intend to enforce the requirements under the FD&C Act. However, FDA may assess the impact that such Non-Device-MDDS and Device-MDDS functions have on the safety and effectiveness of the device function(s) in the multiple function device product. FDA intends to provide recommendations on the regulation of such products with multifunctionality in a separate guidance document.