Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Risk Management Operations
Recall Branch

Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Defects or performance failures of marketed medical devices can pose serious risks to public health. Recalls serve both to correct a defect in current and future devices and to notify users of potential risks and steps to minimize the impact of device failure or malfunction. Medical device recalls include voluntary recalls, either initiated by a firm on its own initiative or in response to a formal request from FDA (covered by 21 CFR part 7, subpart C), and mandatory recalls ordered by FDA under section 518 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 360h] and 21 CFR part 810.[1] Typically, the medical device recall process under 21 CFR part 7 subpart C is initiated and coordinated by the firm and classified, monitored, and terminated by FDA district offices and the Center for Devices and Radiological Health (CDRH).

The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct violative devices or remove them from the marketplace when correction or removal is necessary to protect the public health. When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines a recall is appropriate, and triggers the initiation of the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. All of these issues can result in inconsistent interpretation of regulations by firms, uncertainty in

[1] This draft guidance does not address mandatory recalls.

firms' regulatory responsibility, and delays between the time a device defect or failure is identified and the time the public is notified.

CDRH recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When new iterations of a device involve changes to device design, it does not necessarily mean that the existing device has been recalled. This draft guidance is intended to clarify when a change to a device constitutes a medical device recall, to distinguish those instances from product enhancements that do not meet the definition of a medical device recall, and to identify the associated regulatory reporting requirements for each. Correctly categorizing a change to a device as a recall or product enhancement impacts the applicability and nature of industry responsibilities and FDA oversight. See 21 CFR part 7 subpart C. Clearly distinguishing medical device recalls from product enhancements will assist FDA and firms in assessing when 21 CFR Part 7 Subpart C should be followed. Additionally, this draft guidance seeks to address concerns that firms may have about making product enhancements.

Reports of corrections and removals under 21 CFR part 806 may be required for corrections and removals regardless of whether the implemented change meets the definition of a medical device recall. See sections V and VI for more information about reporting requirements under 21 CFR part 806 for recalls and product enhancements, respectively. This guidance does not address when changes to marketed devices trigger new premarket submissions.

This guidance is organized in a question-and-answer format, providing responses to questions that FDA believes are helpful in properly identifying medical device recalls.

Throughout this guidance the term "you" refers to manufacturers as defined in 21 CFR 806.2(g).

This draft guidance does not address radiation defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050.

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 guidances means that something is suggested or recommended, but not required.

II. Definitions

Recall

As defined at 21 CFR 7.3(g), "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it

administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery." Recall also does not include a product enhancement, as defined by this guidance. The "Recall Identification" section of this guidance document is intended to illustrate some of the common violations that render a device violative and within the definition of a recall.

A recall may be undertaken voluntarily at any time at the initiative of manufacturers and distributors under 21 CFR 7.46, or at the request of the FDA under 21 CFR 7.45. Such requests are directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

Product Enhancement

FDA's regulations do not define product enhancement. For purposes of this guidance document, product enhancement means a change or improvement to a non-violative device as part of continuous device improvement activities. Product enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the product easier to manufacture, and changes to the appearance of the device that do not affect its use. A product enhancement is both (1) a change to improve the performance or quality of a device, and (2) *not* a change to remedy a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321 et seq.] caused by the device. A product enhancement is not a medical device recall.

Stock Recovery

Stock recovery means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned by, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use (21 CFR 7.3(k) and 21 CFR 806.2(l)). A stock recovery is not a recall.

Market Withdrawal

Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation, e.g., normal stock rotation practices or routine equipment adjustments and repairs (21 CFR 7.3(j) and 21 CFR 806.2(h)). A market withdrawal is not a recall.

Correction

Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location (21 CFR 7.3(h) and 21 CFR 806.2(d)). Depending on the circumstances involved, a correction can be a recall or product enhancement.

Removal

Removal means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. (21

CFR 806.2(i)). Depending on the circumstances involved, a removal can be a recall or product enhancement.

III. Recall Identification

Q: Is your product a device?

A: The recall identification procedures described in this guidance apply to all products that meet the definition of "device" in section 201(h) of the FD&C Act [21 U.S.C. 321(h)]. All other products, including electronic products that do not meet the definition of a device, are outside the scope of this guidance document.

Q: Are you considering making a change to your device?

A: For purposes of this guidance, the significant distinction between a medical device recall and a product enhancement is the reason for changing the medical device. A change to the device includes but is not limited to changes to: 1) the device design; 2) the manufacturing process; 3) the device labeling, as defined at section 201(m) of the FD&C Act [21 U.S.C. 321(m)] (including updating the labeling of a distributed product); and 4) marketing practices (e.g., a removal of the device from the market). If you are not considering a change to your device, then you are not conducting a removal or correction, and your actions do not fall within the scope of a medical device recall or a product enhancement.

The distinction between a recall and product enhancement depends on an assessment of each change individually, as well as the impact of all such changes on the device as a whole. In many instances, multiple changes to a device may be implemented in a single update. If you are considering multiple changes to your device, then you should apply the methodology identified in this guidance for each change under consideration. If any change or group of changes addresses a violation of the FD&C Act, then that change would generally constitute a medical device recall.

Q: Are the devices to which you are considering making changes on the market?

A: Only marketed devices can be recalled.[2] Changes to devices that have not entered the market fall within the definition of a stock recovery and are explicitly excluded from the definition of a recall.[3]

[2] For purposes of identifying a medical device recall, devices distributed for use in a clinical study under an Investigational Device Exemption (IDE) are not considered to be marketed.

3 However, if a change is made to newly manufactured, unreleased lots of a model that is in commercial distribution, that change is not considered a stock recovery.

IV. Differentiating Violative Devices from Non-Violative Devices

Only changes to devices to remedy a violation of the laws administered by FDA and against which the agency would initiate legal action fall within the definition of a medical device recall. For example, if a device is being corrected to address a Quality System violation (see 21 CFR part 820), the correction would generally be considered a recall.

Changes to non-violative devices are considered to be product enhancements and not medical device recalls. The questions in this section are intended to help identify the existence of a violative device.

Q: Is the device to which you are considering making changes failing to meet any specification or failing to perform as intended?

A: FDA generally considers devices that fail to meet specifications[4] and devices that fail to perform as intended to be of a quality below what they purport or are represented to possess, which would render them adulterated under section 501(c) of the FD&C Act [21 U.S.C. 351(c)]. Changes to or removals of these devices to correct these violations would generally constitute recalls.

A change made to improve a level of safety performance that was known, predicted, and stable at the time the device was cleared or approved does not typically mean that the underlying product was violative. A change to improve the performance or quality of a legally marketed, non-violative device is a product enhancement and not a medical device recall. Such a change may be reportable under 21 CFR 806.10 (see section VI, Product Enhancement Reporting Requirements).

A firm's risk management activities will help provide a reference for known failure modes and expected or estimated failure rates. An increase in overall failure rate,[5] increase in a single failure mode rate,[6] or the identification of a new failure mode would indicate a failure to perform as intended. A change to the marketed device to address a failure to perform to specifications, or a failure to perform as intended, would constitute a medical device recall.

[4] Manufacturers of most medical devices are required to comply with the requirements for design controls when establishing specifications for the devices they manufacture. See 21 CFR 820.30.

[5] For purposes of this guidance, "overall failure rate" means the total rate of device failure regardless of cause.

[6] For purposes of this guidance, "failure mode" means a specific method or type failure. For example, a stent delivery device with balloon inflation could have known failure modes of (1) rupture due to over inflation and (2) rupture due to material degradation.

Examples: Design Changes and New Failure Mode Identification

An implantable device was approved with an expected/estimated battery life of 5 years under normal conditions of use.

- The supplier of the battery makes technology changes to the battery that will yield an expected battery life of 5.5 years under the same conditions of use. This is a product enhancement and the prior product would not be subject to a recall.

- The supplier of a battery has indicated obsolescence of the current technology. A new supplier is sought out by the manufacturer. The new supplier can deliver a battery that has a 6 year expected life span. This would be considered a product enhancement.

- The manufacturer of a device has two suppliers of a battery. When assessed in aggregate, the overall device population seems to meet the device specifications for a battery life of five years. However, upon analysis of several reports of premature battery depletion, it appears that all of the reports involve only one of the suppliers and not the other. When analyzed separately, the lifespan of the batteries from one of the suppliers is found to be four years, and the batteries from the other supplier last six years. Further investigation reveals that it is a problem in the manufacturing process of the supplier whose batteries last four years that leads to the premature battery depletion. This segment of the device population may be subject to a recall.

Q: Is the labeling for the device to which you are considering making changes false or misleading, does it fail to have adequate directions for use, or does it otherwise violate the FD&C Act or FDA regulations?

A: Devices with false or misleading labeling are misbranded under section 502(a) of the FD&C Act [21 U.S.C. 352(a)]. Devices that fail to provide adequate directions for use as defined at 21 CFR 801.5 are misbranded under section 502(f) of the FD&C Act [21 U.S.C. 352(f)] (unless exempt).[7] Devices that fail to meet other applicable labeling requirements identified in 21 CFR parts 801 and 809, subpart B, are also in violation of the laws administered by FDA.

[7] Prescription devices that meet the requirements of 21 CFR 801.109 are exempt from section 502(f)(1) of the FD&C Act.

Labeling is defined in section 201(m) of the FD&C Act as "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." The term "accompanying such article" is not restricted to labels that are attached to or in the article or package in which it is transported,[8] and labeling can include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, and information on a manufacturer's web page.

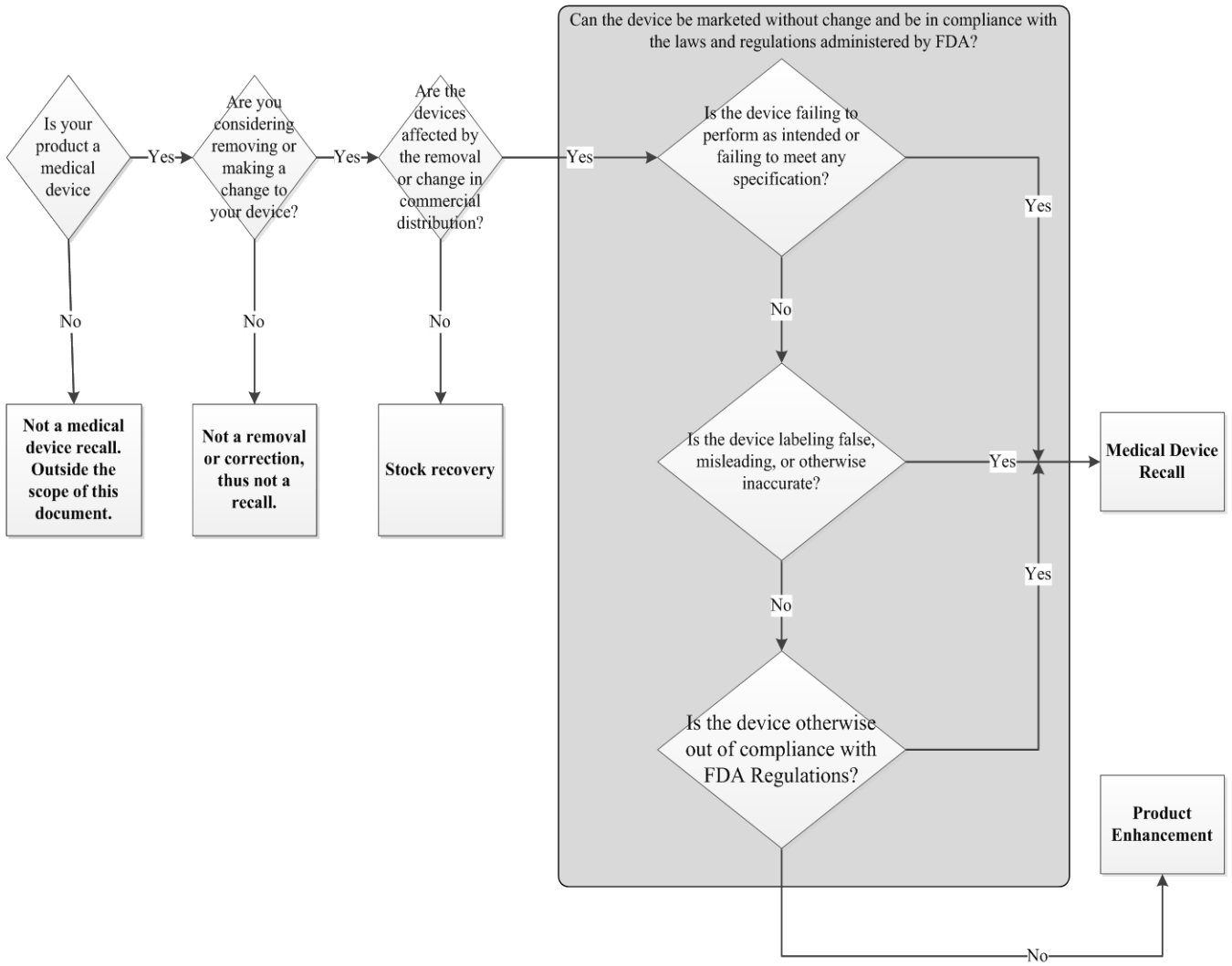
A change to a marketed device to address false or misleading labeling or other labeling violations would generally constitute a medical device recall. Such changes may be reportable under 21 CFR part 806 (see section V Recall Reporting Requirements). However, the addition of a new warning or other changes to the labeling of a *non-violative* device would not be meet the definition of a recall, but may still be reportable (see section VI, Product Enhancement Reporting Requirements).

Q: Are you otherwise out of compliance with FDA regulations?

A: You should conduct a careful, thorough, and adequate assessment for each proposed change to your device. If the result of your assessment indicates that the change is made to a violative marketed device to bring it into compliance with the laws administered by FDA, then the change would most likely constitute a medical device recall.

[8] See, for example, *Kordel v. United States*, 335 U.S. 345, 349-350 (1948).

271 Recall Decision Making Flow Chart



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V. Recall Reporting Requirements

Once a manufacturer determines that a proposed change meets the definition of a medical device recall, the manufacturer should assess whether a report to FDA is required. Under 21 CFR part 806, Medical Devices; Reports of Corrections and Removals,[9] manufacturers must submit a correction and removal report (806 report) to FDA for any correction or removal of a medical device that was initiated by such manufacturer 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 health risk, with certain exceptions.[10]

Q: If you have determined that the change is a medical device recall, must you file an 806 report?

A: Pursuant to 21 CFR 806.10(a), a manufacturer must submit an 806 report to FDA when the correction or removal is initiated to (1) reduce a risk to health posed by the device or (2) remedy a violation of the FD&C Act caused by the device which may present a risk to health, unless the information has already been reported to FDA under 807.10(f), or the change qualifies as a market withdrawal, routine servicing, or stock recovery, as defined at 806.2.

Given the overlap in the definition of a recall and the criterion for an 806 report at 21 CFR 806.10(a)(2), a recall must be reported to FDA as long as the violation targeted by the recall may present a risk to health. A risk to health means (1) a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of or exposure to the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.[11]

A required 806 report must be submitted to FDA within 10 working days from the time the firm initiates the recall, in accordance with 21 CFR 806.10(b). Regulatory requirements regarding what must be included in an 806 report are available at 21 CFR 806.10(c). In general, reports should be made to the FDA District Office in which the reporting facility is geographically located.

The device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under part 806 must maintain records of the correction or removal. Regulatory requirements regarding records of corrections and removals not required to be reported to FDA may be found at 21 CFR 806.20.

Under the regulations, the manufacturer or importer must retain all records for a period of two years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. If there is a change in ownership, records

[9] 21 CFR part 806 establishes correction and removal reporting requirements for manufactures and importers. For purposes of this guidance, part 806 reporting requirements are described as they apply to device manufacturers.

[10] 21 CFR 806.10(a)

[11] 21 CFR 806.2(j).

required to be maintained must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.[12]

Q: How do you determine whether a violation targeted by a medical device recall may present a risk to health?

A: Because the two parts of the definition of risk to health at 21 CFR 806.2(j) mirror the definitions of class I and class II recalls at 21 CFR 7.3(m)(1) and (2), CDRH interprets the requirement to report under 21 CFR part 806 to apply to recalls that are classified as class I or class II under 21 CFR Part 7.

Class I and II recalls are defined under 21 CFR 7.3(m) as:

- Class I - a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II - a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

A Class III recall is defined at 21 CFR 7.3(m)(3) as "a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences." Because violations targeted by class III recalls would generally not pose a "risk to health" under 21 CFR part 806, 806 reports are generally not required for events categorized as class III.

If an 806 report is not required under 21 CFR part 806, you may still submit a voluntary report.

To determine whether the use of, or exposure to, the device being recalled poses a "risk to health" as defined at 21 CFR 806.2(j),[13] FDA recommends that you conduct an analysis or assessment of the risk to health associated with the device. One method of evaluating this is through a Health Hazard Evaluation (HHE). The following factors are identified by 21 CFR 7.41 to be considered during an HHE evaluation:

- Whether any disease or injuries have already occurred from use of the product.
- Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion should be supported as completely as possible by scientific documentation or statements that the conclusion is the opinion of the individuals making the health hazard determination.

[12] 21 CFR 806.20(c).

[13] Under 21 CFR 806.2(j), a risk to health means (1) a reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) that use of or exposure to the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

- Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention to those individuals who may be at greatest risk.
- Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
- Assessment of the likelihood of occurrence of the hazard.
- Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

Q: What are the factors FDA considers in assessing your evaluation of the likelihood of adverse health consequences associated with the medical device recall?

A: In addition to the HHE factors identified in 21 CFR part 7, FDA considers the following points in determining the relative degree of health hazard associated with the device being recalled.[14] For purposes of this guidance, the relative degree of health hazard is FDA's assessment of the risk to health under 21 CFR part 806.

- Has the HHE identified multiple problems with the device that present different or multiple risks? It is appropriate to conduct a separate HHE for each device defect or change in addition to an HHE for all of the defects and/or changes together.

- Has the risk been assessed based on the presumption that no action has or will be taken by the firm or FDA to correct the problem? FDA assesses risk based on the device as it exists in distribution without any remedial action taken.

- Not all devices in the recalled lots may be defective. Some of the devices that are not within specifications may have a defect but never malfunction. Furthermore, not all devices that malfunction may cause injury. Has this information been considered?

- Has the number of devices expected to fail and cause injury been estimated based on a technical assessment of the device and the defect, the intended use, the usual safety and performance of the product, and what is known about the failure mode?

- Have reported complaints and medical device reports (MDRs) been considered when estimating the number of devices that may fail and cause injury? These may provide a lowest estimated frequency and severity of injury from the defect. The technical assessment may then raise the final estimate. The lack of reported injuries does not decrease the level of risk assigned.

- If available information is incomplete, have you made appropriate and accurate assumptions regarding the missing information? In some instances, it may be appropriate to assume the worst case and estimate the likelihood and risk of injury to be the highest that might potentially occur.

[14] Additional information on CDRH's Health Hazard Evaluation is located at http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/ucm217880.htm.

- Has the HHE been completed for both the population at greatest risk of injury and for the entire population that may use or be treated or diagnosed by the device?

- Has the HHE considered how easily the user can detect the defect or device malfunction and take mitigating actions to reduce a risk to health? You should not assume that the user or patient will always detect the problem before harm occurs.

- Has the risk been assessed based on the range of immediate and long term health consequences that might be expected with the device problem?

- Has the risk been assessed based on a full analysis of all possible health risks? For example, the need for surgery is a consequence of the device malfunction and should be included as a risk in the assessment. Injury should be defined broadly to include significant psychological distress and errors in patient medical management.

A failure to consider all relevant issues could result in an inaccurate relative degree of health hazard assessment.

VI. Product Enhancement Reporting Requirements

Q: If you have determined that the change is a product enhancement, and not a medical device recall, do you have any 806 reporting obligations?

A: Under 21 CFR 806.10(a)(1), an 806 report is required when a correction or removal is initiated to "reduce a risk to health posed by the device."[15] Thus, as long as your change is initiated to reduce a risk to health posed by your device, even if your change is not a recall, you must submit an 806 report unless all the information has already been provided to FDA under the Medical Device Reporting requirements (21 CFR Part 803).[16] Some examples of changes that FDA would consider reportable under 806 include the addition of a new warning to a device's label in order to reduce a health risk, a manufacturing change to a sterile device to reduce the likelihood of contamination, or a design change to improve a product's safety profile.

An 806 report submitted for product enhancements should be identified as such by the manufacturer. If FDA concurs with your assessment that the correction or removal is a product enhancement, the agency will not treat the report as a recall but will determine the appropriate premarket and postmarket actions necessary to address the information contained in the 806 report.

[15] See 21 CFR 806.2(j) for the definition of "risk to health.
[16] 21 CFR 806.10(f).

VII. Additional Regulatory Requirements

Q: Once you have determined whether the change is a medical device recall or a product enhancement and whether you must report to FDA under 21 CFR part 806, do you have any additional regulatory obligations?

A: This guidance does not attempt to address all regulatory obligations associated with a change to a marketed device. Whether a change to a marketed device constitutes a recall or a product enhancement, you should carefully review the change under applicable regulations and guidance documents to determine whether the change triggers a requirement for a premarket submission, for example under 21 CFR 807.81(a)(3) or 814.39.[17, 18]

[17] See "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)" (issued January 10, 1997).

[18] For medical devices approved under a Premarket Approval application, refer to "Guidance for Industry and FDA Staff; Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (issued December 11, 2008).