

*Contains Nonbinding Recommendations*

# **Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID- 19) Public Health Emergency**

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## **Guidance for Industry, Clinical Laboratories, Healthcare Facilities, Pathologists, and Food and Drug Administration Staff**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health (CDRH)  
Office of Product Evaluation and Quality (OPEQ)**

# Preface

## Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

## Additional Copies

Additional copies are available from the FDA webpage titled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, the FDA webpage titled “Search for FDA Guidance Documents,” *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an additional copy of the guidance. Please include the document number 20029 and complete title of the guidance in the request.

## Questions

For questions about this document, contact 1-888-INFO-FDA or [CDRH-COVID19-DigitalPathology@fda.hhs.gov](mailto:CDRH-COVID19-DigitalPathology@fda.hhs.gov).

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# **Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID- 19) Public Health Emergency**

## **Guidance for Industry, Clinical Laboratories, Healthcare Facilities, Pathologists, 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 or the Agency) plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of devices for remote reviewing and reporting of scanned digital images of pathology slides (“digital pathology slides”) (hereinafter these devices will be referred to as “remote digital pathology devices”) during this pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by HHS, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled “Process for Making Available Guidance Documents Related to Coronavirus Disease

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2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, 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**

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19, and mobilized the Operating Divisions of HHS.<sup>1</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>2</sup>

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability of remote digital pathology devices during this public health emergency. Increased availability of these devices may help to facilitate continuity of patient care by preventing disruptions to critical pathology services rendered by clinical laboratories, hospitals, and other healthcare facilities, and by reducing healthcare personnel contact and risk of exposure to SARS-CoV-2.

## **III. Scope**

The enforcement policy described in this guidance applies to the following devices (“digital pathology devices”), which may be used during the COVID-19 public health emergency, when they are intended for use in remote reviewing and reporting of digital pathology slides:

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<sup>1</sup> The declaration was renewed on April 21, 2020, effective April 26, 2020. Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>2</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

**Table 1**

<b>Classification Regulation</b>	<b>Device Type</b>	<b>Product Code<sup>3</sup></b>	<b>Class</b>
21 CFR 864.1860	Automated Digital Image Manual Interpretation Microscope	OEO	II
21 CFR 864.3700	Whole Slide Imaging System	PSY	II
21 CFR 864.3700	Digital Pathology Image Viewing and Management Software	QKQ	II
21 CFR 864.3700	Digital Pathology Display	PZZ	II

Although the digital pathology devices listed above are typically used in clinical laboratories, hospitals, and other healthcare facilities, as further discussed in Section IV below, many of these devices possess the capability for reviewing and reporting of digital pathology slides from remote locations.

## **IV. Policy**

### **A. Overview**

In the context of the COVID-19 public health emergency, expanding the availability of remote digital pathology devices may help facilitate pathology services while reducing healthcare personnel contact and risk of potential exposure to SARS-CoV-2.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. 263a) require that clinical laboratories, including those within hospitals and other healthcare settings, obtain a certificate before accepting materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or the impairment of, or assessment of the health of human beings.<sup>4</sup> Digital pathology devices have not been cleared for home use or categorized as waived by FDA and as a result, these devices have been limited to use in clinical laboratories, hospitals, and other healthcare settings that are CLIA-certified to perform nonwaived testing. However, in light of the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) issued a memorandum on March 26, 2020, describing its exercise of enforcement discretion to ensure pathologists may review pathology slides and images remotely. The CMS memorandum states that laboratories that choose to utilize temporary testing sites (e.g., for remote review and reporting of slides/images) may do so if certain criteria outlined in the memorandum are met.<sup>5</sup>

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<sup>3</sup> For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpCD/classification.cfm>.

<sup>4</sup> For more information, see FDA's guidance "Administrative Procedures for CLIA Categorization: Guidance for Industry and Food and Drug Administration Staff", available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/administrative-procedures-clia-categorization>.

<sup>5</sup> See the Centers for Medicare & Medicaid Services Memorandum, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, March 26, 2020, <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>.

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In general, manufacturers of the digital pathology devices listed in Table 1 are required to submit a premarket notification under section 510(k) of the FD&C Act and receive FDA clearance prior to marketing these devices in the United States, as well as comply with post-marketing requirements.

FDA recognizes that greater access to remote digital pathology devices may help facilitate the remote reviewing and reporting of pathology slides during this public health emergency which, in turn, may help facilitate continuity of patient care and reduce healthcare personnel contact and risk of exposure to SARS-CoV-2. For that reason, for the duration of the COVID-19 public health emergency, FDA does not intend to object to:

- modifications to the FDA-cleared indications, functionality, hardware and/or software, of digital pathology devices identified in Table 1 above to provide for use in a remote setting, or
- the marketing of new digital pathology devices of the types identified in Table 1 that are intended for use in remote settings and that are not currently 510(k) cleared for any use,

without compliance with the following regulatory requirements, where such devices do not create an undue risk in light of the public health emergency: submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,<sup>6</sup> Good Manufacturing Practice requirements in 21 CFR Part 820, and Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20.

Additionally, for remote digital pathology devices subject to this policy, FDA does not intend to enforce compliance with the special controls identified in 21 CFR 864.1860 (which are described in a special controls document for the submission of immunohistochemistry applications to the FDA<sup>7</sup>) and 21 CFR 864.3700 (83 FR 22), which includes requirements for the content of a premarket notification submission for a whole slide imaging system, where such devices or modifications do not create an undue risk in light of the public health emergency.

FDA believes such devices will not create such an undue risk where the performance and labeling elements in Section IV.B are met.

## **B. Labeling and Performance**

FDA believes such devices will not create such an undue risk when the following circumstances related to the performance of the device and the product labeling, including instructions specific to remote use, are present. FDA encourages firms to discuss any alternatives to these recommendations with FDA ([CDRH-COVID19-DigitalPathology@fda.hhs.gov](mailto:CDRH-COVID19-DigitalPathology@fda.hhs.gov)).

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<sup>6</sup> For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to “Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff,” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

<sup>7</sup> For more information, see “Guidance for Submission of Immunohistochemistry Applications to the Food and Drug Administration,” <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/guidance-submission-immunohistochemistry-applications-food-and-drug-administration-final-guidance>.

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FDA recommends that remote digital pathology devices use labeling that helps users better understand the device or device modifications, including instructions specific for remote use, such as:

- a. Instructions for clinical laboratories, hospitals, and other healthcare facilities to help them determine if remote reviewing and reporting of digital pathology slides is feasible and appropriate based on an evaluation of their own information technology (IT) infrastructure and remote use environment for individual pathologists. FDA recommends that laboratories and hospitals consider performing a validation study where they deem necessary before remote reviewing and reporting of digital pathology slides at a remote location.
- b. Instructions recommending that pathologists using such devices during the COVID-19 public health emergency use their clinical judgment to determine whether the quality of the images from the remote digital pathology devices are sufficient for interpretation of the pathological images.

FDA recommends that manufacturers consider evaluating the performance of the device in accordance with the following FDA recognized standards, including (as applicable):

- ANSI/AAMI ES60601-1:2005 (R2012) and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 – *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014 – *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*

Additionally, while no device-specific performance recommendations are included in this enforcement policy, CLIA regulations and State law (including those related to performance) apply, although some CLIA regulations may be subject to CMS enforcement policies during this public health emergency.<sup>8</sup>

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).<sup>9</sup> For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).<sup>10</sup>

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<sup>8</sup> See the Centers for Medicare & Medicaid Services Memorandum, Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, March 26, 2020, <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and-clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>.

<sup>9</sup> <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

<sup>10</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

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In addition, manufacturers should develop and implement appropriate cybersecurity controls to ensure device cybersecurity and maintain functionality and safety for remote digital pathology devices. The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)<sup>11</sup>
- [Postmarket Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)<sup>12</sup>
- [FDA FACT SHEET: The FDA's Role in Medical Device Cybersecurity - Dispelling Myths and Understanding Facts](#)<sup>13</sup>

## **C. Additional Helpful Resources**

The following online resources may also be helpful in evaluating the device:

- [Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices - Guidance for Industry and Food and Drug Administration Staff](#)<sup>14</sup>
- [Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)<sup>15</sup>
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff](#)<sup>16</sup>
- [Software as a Medical Device \(SAMD\): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff](#)<sup>17</sup>
- [Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff](#)<sup>18</sup>
- [Design Considerations and Pre-market Submission Recommendations for Interoperable Devices - Guidance for Industry and Food and Drug Administration Staff](#)<sup>19</sup>

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<sup>11</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

<sup>12</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>.

<sup>13</sup> <https://www.fda.gov/media/123052/download>.

<sup>14</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-digital-pathology-whole-slide-imaging-devices>.

<sup>15</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>.

<sup>16</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

<sup>17</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/software-medical-device-samd-clinical-evaluation>.

<sup>18</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>.

<sup>19</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>.