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Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

April 2020

**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 the 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) 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 which is the specific general docket for the Center for Devices and Radiological Health (CDRH) 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 to receive an additional copy of the guidance. Please include the document number 20030 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-FetalMonitors@fda.hhs.gov.

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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 and capability of non-invasive fetal and maternal monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and potential exposure to COVID-19 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 the Department of Health and Human Services (HHS), including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

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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 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) 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 “severe acute respiratory syndrome coronavirus 2” (SARS-CoV-2) and the disease it causes has been named Coronavirus Disease 2019 (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19, effective January 27, 2020, and mobilized the Operating Divisions of HHS. The declaration was renewed for another 90 days on April 21, 2020, effective April 26, 2020.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA believes the policy set forth in this guidance will help address these urgent public health concerns by helping to expand the availability and capability of non-invasive fetal and maternal monitoring devices. Modified use of these devices may increase access to important prenatal data without the need for in-clinic visits and facilitate patient management by health care providers while reducing the need for in-office or in-hospital services during the COVID-19 public health emergency. Increased utilization of non-invasive fetal and maternal monitoring devices may ease burdens on hospitals and other healthcare facilities and reduce the risk of exposure for patients and health care providers to SARS-CoV-2.

III. Scope

The enforcement policy in this guidance applies to the following non-invasive fetal and maternal monitoring devices that measure or detect fetal heart rate, maternal heart rate, and/or uterine activity, that are used to support patient monitoring in a home setting, and which may be used

¹ Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, effective Jan. 27, 2020, and April 21, 2020, effective April 26, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² 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/>.

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during the COVID-19 public health emergency. The non-invasive fetal and maternal monitoring devices to which this guidance applies can be divided into two categories:

- Fetal dopplers that lay users (e.g., patient, caregiver) could be instructed to use in a home setting under the direction of a health care provider via prescription (Table 1)
- Fetal and maternal monitoring devices that could be used by a health care provider via prescription in a home setting (Table 2)

Table 1 - Fetal dopplers that lay users could be instructed to use in a home setting under the direction of a health care provider via prescription

Classification Regulation	Device Type	Product Code³	Device Classification
21 CFR 884.2660	Fetal ultrasonic monitor	KNG	II

Table 2 - Fetal and maternal monitoring devices that could be used by a health care provider via prescription in a home setting

Classification Regulation	Device Type	Product Code⁴	Device Classification
21 CFR 884.2600	Fetal cardiac monitor	KXN	II
21 CFR 884.2640	Fetal phonocardiographic monitor	HFP	II
21 CFR 884.2660	Ultrasonic fetal heart rate monitor	HEL	II
21 CFR 884.2720	External (for use in clinic) uterine contraction monitor	HFM	II
21 CFR 884.2720	Uterine electromyographic monitor	OSP	II
21 CFR 884.2740	Perinatal monitoring system	HGM	II
21 CFR 884.2960	Obstetric ultrasonic transducer	HGL	II

In general, manufacturers of these non-invasive fetal and maternal monitoring devices are required to submit a premarket notification pursuant to section 510(k) of the FD&C Act and 21 CFR 807.81 to FDA and receive FDA clearance prior to marketing these devices in the United States, as well as comply with post-marketing requirements.

The fetal ultrasonic monitor devices described in Table 1 are more commonly referred to as fetal dopplers. Fetal dopplers are prescription handheld devices traditionally used in a clinical setting to detect fetal heart rate starting at 10-12 weeks of gestation. Fetal dopplers provide a real time numerical output of fetal heart rate and are typically used to “spot check” fetal heart rate. Fetal dopplers are distinct from the ultrasonic fetal heart rate monitors described in Table 2, which are prescription devices traditionally used in a clinical setting that use ultrasound transducers placed on the maternal abdomen to measure fetal heart rate over the duration of a monitoring session. The ultrasound transducers are connected to an electronic screen that graphically displays fetal heart rate over the monitoring period. The graphical output of an ultrasonic fetal heart rate

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

⁴ *Ibid*

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monitor allows health care providers to assess changes in fetal heart rate over time.

The non-invasive fetal and maternal monitoring devices in Table 1 and Table 2 may have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection to transmit a patient's measurements directly to their health care provider or other monitoring entity.

IV. Policy

A. Overview

In the context of the COVID-19 public health emergency, expanding the capability of currently marketed non-invasive fetal and maternal monitoring devices may help facilitate patient care while reducing patient and healthcare provider contact and risk of exposure to SARS-CoV-2 by helping expand the availability of these devices to patients who require fetal and/or maternal monitoring for conditions unrelated to COVID-19 so they can be monitored outside of health care facilities. For that reason, and as described in more detail below, for the duration of the COVID-19 public health emergency, FDA does not intend to object to limited modifications to the indications, functionality, hardware and/or software of the FDA-cleared non-invasive fetal and maternal monitoring devices listed in Tables 1 and 2, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,⁵ where such modification does not create an undue risk in light of the public health emergency. Examples of such modifications include:

- For devices previously cleared only for use in hospitals or other health care facilities, a change to the indications or instructions regarding use in the home setting;⁶
- Modifications to devices, including changes in hardware or software, to allow for increased remote monitoring capability; and,
- Modifications to devices to make the device more mobile for facilitating transfer into and out of a transportation vehicle and into a patient's home.

⁵ 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>.

⁶ The modification described is focused on these devices being modified for use in a home setting with a prescription. Devices that are modified for direct over-the-counter (OTC) use are outside the scope of the policy in this guidance.

B. Modifications to the Indications and Functionality of Fetal and Maternal Monitoring Devices

1. Prescription use fetal dopplers that lay users could be instructed to use in a home setting under the direction of a health care provider

For the duration of the public health emergency, FDA does not intend to object to limited modifications to the FDA-cleared indications, functionality, hardware, and/or software of fetal dopplers identified in Table 1 above to allow the devices to be used by a lay user in a home setting under the direction of a health care provider without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. FDA believes such limited modifications to devices will not create such an undue risk where the performance and labeling elements in Section IV.C and Section IV.D.1 are met.

Examples of circumstances where FDA currently believes a modification to a device in Table 1 would not create such undue risk include:

- 1) The fetal doppler display is modified to facilitate understanding by a lay user and/or provide instruction to a lay user, including display of fetal heart rate. For such a modification, the fetal doppler should also include labeling (see Section IV.D.1. below) that sufficiently reduces the risk of use by including information that the lay user can use to provide the necessary instructions for users not trained in its use.
- 2) The fetal doppler is modified to incorporate software and/or hardware intended to facilitate remote access where the modification does not directly affect the fetal heart rate measurement algorithms (e.g., addition of wireless or Bluetooth capability).

Examples of circumstances where FDA currently believes a modification to these devices would create such an undue risk include:

- 1) The fetal doppler is labeled for over-the-counter sale directly to lay users.
- 2) The fetal doppler provides information beyond a real time numerical fetal heart rate output and an average fetal heart rate output.
- 3) The fetal doppler provides a pulsed output.
- 4) The device is labeled or otherwise modified for use at a lower gestational age than indicated per its 510(k) clearance.

2. Fetal and maternal monitoring devices that could be used by a health care provider via prescription in a home setting

For the duration of the public health emergency, FDA does not intend to object to modifications to the FDA-cleared indications, functionality, hardware and/or software of other maternal and fetal monitoring devices traditionally used in a clinical setting to measure and display fetal heart rate, maternal heart rate, and/or uterine activity over a monitoring session (identified in Table 2

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above), to allow the devices to be used in a home setting by a health care provider without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. FDA believes such limited modifications to such devices will not create such an undue risk where the performance and labeling elements in Section IV.C. and Section IV.D.2 are met.

Examples of circumstances where FDA currently believes a modification to these devices would not create such undue risk include:

- 1) The device is modified to include software and/or hardware intended to facilitate remote access where the modification does not directly affect the fetal heart rate, maternal heart rate, or uterine activity measurement algorithms (e.g., addition of wireless or Bluetooth capability, addition of a mobile medical application to facilitate monitoring of labor progress or detect fetal distress⁷).
- 2) Hardware or software changes intended to make the device more mobile or facilitate transfer into and out of a transportation vehicle and into a patient's home (e.g., eliminate wired connection between transducer and monitor, changing the device interface to allow monitoring display and/or device controls on a tablet or mobile phone).

Examples of circumstances where FDA currently believes a modification would create such an undue risk include:

- 1) The device is labeled for over-the-counter sale directly to lay users.
- 2) The device is labeled for use by lay users under the direction of a health care provider.
- 3) The device applies an algorithm to transform a physiological parameter into a novel index or alarm that may aid a health care professional diagnosis of an obstetric condition.
- 4) The device is labeled or otherwise modified for use at a lower gestational age than indicated per its 510(k) clearance.

C. Validation of Modifications to Fetal and Maternal Monitoring Devices

Under design controls, manufacturers are required to conduct verification and validation (21 CFR 820.30(f) and (g)). Verification and validation include procedures to ensure that design outputs meet design inputs and that devices conform to defined user needs and intended uses. In designing, evaluating, and validating modifications made under this policy to hardware and/or software, FDA recommends doing so in accordance with FDA recognized standards for the specific device type, including (as applicable):

⁷ Consistent with existing policy in section 520(o)(1) of the FD&C Act and the FDA guidance "Policy for Device Software Functions and Mobile Medical Applications" (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>), this type of change would be subject to FDA regulation and generally would require submission of a 510(k).

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- 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*
- ANSI/AAMI/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*
- IEC 60601-1-11:2015 – *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other FDA-recognized, applicable collateral/particular standards in the 60601-1 family
- AAMI TIR69: 2017 – *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017 – *American National Standard for Evaluation of Wireless Coexistence*
- ANSI/AAMI/IEC 62304 – *Medical Device Software – Software Life Cycle Processes*

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).⁸ 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](#).”⁹

In addition, for any such changes, manufacturers should develop and implement appropriate cybersecurity controls to assure device cybersecurity and maintain device functionality and safety. The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)¹⁰
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)¹¹
- [Postmarket Management of Cybersecurity in Medical Devices](#)¹²

⁸ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

¹⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>

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

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

D. Labeling of Modified Devices

1. Fetal dopplers that lay users could be instructed to use in a home setting under the direction of a health care provider via prescription

For fetal dopplers, identified in Table 1, FDA recommends that the labeling helps users better understand the device modifications, such as labeling that:

- 1) Highlights the differences in design, as applicable, compared to the unmodified, FDA-cleared or FDA-approved version of the product, along with instructions for mitigating any known risks associated with these differences.
- 2) Includes a clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.
- 3) Includes adequate instructions for use for the intended lay user and indicated environment(s) of use (e.g., home) with appropriate lay terminology in a separate patient labeling. FDA believes the following recommended labeling elements will help users understand and properly use the modified device:
 - a. Information regarding the appropriate patient population (e.g., gestational age, singleton pregnancy).
 - b. Step-by-step instructions (e.g., step-by-step diagram or training videos on how to use the device, application of the gel, positioning/repositioning of the fetal doppler).
 - c. A prominent notice about information on the use of the device and any applicable warnings, which we recommend include:
 - Compatible ultrasound gel (e.g., gel provided for use with the fetal doppler).
 - Notice that decreased fetal movement should be immediately reported to a health care provider.
 - Notice that the device should only be used for medical purposes, and under the direction of a health care provider.
 - Potential that prolonged ultrasound exposure on the fetus may be harmful (e.g., fetal heart rate measurement should not be completed more frequently than recommended by a health care provider).
 - Possible consequences of misinterpretation of maternal heart rate as fetal heart rate (e.g., misinterpretation may lead to false reassurance and failure to seek medical attention when necessary, or false alarm which could lead to unnecessary office visits).
 - d. Information to mitigate against misinterpretation for which FDA recommends including:
 - Information on typical fetal heart rate ranges.
 - Information on typical maternal heart rate ranges and suggested methods of checking maternal pulse as a reference, if possible.
 - e. Troubleshooting information for when fetal heart rate cannot be detected (e.g.,

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reposition device or use additional ultrasound gel), including information on what to do after following troubleshooting recommendations (e.g., immediately report to health care provider).

FDA also recommends that manufacturers use the FDA guidance document, [Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Staff](#)¹³ for additional recommendations regarding developing patient labeling.

FDA recommends that health care providers ensure lay users receive the patient labeling for the fetal doppler developed by the manufacturer and provide supplemental training as necessary. In addition, FDA recommends that health care providers ensure lay users are provided ultrasound gel for use with the fetal doppler.

2. Fetal and maternal monitoring devices that could be used by a health care provider via prescription in a home setting

For the other maternal and fetal monitors, identified in Table 2, FDA recommends that the labeling helps users better understand the device modifications, such as labeling that:

- 1) Highlights the differences in design, as applicable, compared to the unmodified, FDA-cleared or FDA-approved version of the product, along with instructions for mitigating any known risks associated with these differences.
- 2) Includes a clear distinction delineating FDA-cleared indications from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.
- 3) For devices previously cleared for use only in a hospital or other health care facility and for which the environment of use has been expanded to include home use, includes adequate instructions for use by a health care provider in the home environment.
- 4) Includes reprocessing instructions for health care providers between multi-patient use.

V. Additional Helpful Resources

The following online resources may also be helpful in evaluating the performance of these products:

- [Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Guidance for Industry and Food and Drug Administration Staff](#)¹⁴

¹³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling>

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers>

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- [Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)¹⁵
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff](#)¹⁶
- [Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff](#)¹⁷
- [Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices: Guidance for Industry and Food and Drug Administration Staff](#)¹⁸
- [Information to Support a Claim of Electromagnetic Compatibility \(EMC\) of Electrically-Powered Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#)¹⁹
- [Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff](#)²⁰
- [Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff](#)²¹
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](#)²²
- [Postmarket Management of Cybersecurity in Medical Devices](#)²³

¹⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>

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

¹⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications>

¹⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>

¹⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices>

²⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use>

²¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>

²² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>

²³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices>