Contains Nonbinding Recommendations

Enforcement Policy for Clinical Electronic Thermometers

Guidance for Industry and Food and Drug Administration Staff

Document issued on November 3, 2023.

This document supersedes "Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" issued in April 2020 and updated in March 2023.

For questions about this document, contact OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices/DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors at (301) 796-7030.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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 20852-1740. Identify all comments with the docket number FDA-2023-N-4372. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00020021 and complete title of the guidance in the request.

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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 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 and public health emergencies (PHEs).

Following the emergence of COVID-19, FDA first issued guidance in April 2020 to provide a policy to help expand the availability of clinical electronic thermometers to address the PHE. At the time, FDA stated that the policy described in the guidance was intended to remain in effect only for the duration of the PHE related to COVID-19 declared by the Secretary of Health and Human Services (HHS) in accordance with section 319 of the Public Health Service Act (PHS Act). On March 13, 2023, FDA announced in the Federal Register notice "Guidance Documents Related to Coronavirus Disease 2019 (COVID-19),"[1] that the guidance document was being revised to continue in effect for 180 days after the expiration of the COVID-19 PHE declaration, and that, during that time, FDA would intend to further revise this guidance, among others. The policies described in this guidance take into account that the April 2020 version of the guidance is intended to remain in effect through November 7, 2023, unless superseded by a final guidance before that date.

Clinical electronic thermometers are used to measure and monitor the body temperature of patients. These devices are an important screening and diagnostic tool to assist in the identification of individuals who have or may have a range of conditions and illnesses, including

[1] See Federal Register notice "Guidance Documents Related to Coronavirus Disease 2019 (COVID-19)" (88 FR 15417), available at https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19 (hereinafter referred to as the "March 13, 2023, Federal Register Notice").

those who may be infected with COVID-19.[2] FDA's previous policies for clinical electronic thermometers were intended to help address urgent public health concerns by helping to expand the availability of clinical electronic thermometers during the COVID-19 PHE, thereby helping to prevent or mitigate potential shortages as the demand increased due to usage at critical locations such as airports, hospitals, and other locations. Since first issuing the guidance "Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" in April 2020, FDA's experience has generally demonstrated that the public health equities weigh in favor of continuing certain enforcement policies for these devices beyond the expiration of the COVID-19 PHE (which expired on May 11, 2023) and the 180-day period announced in the March 13, 2023, Federal Register notice. More specifically, FDA has evaluated the benefits and risks to patients and healthcare providers of maintaining certain enforcement policies, including identifying certain device types for which continued enforcement policies might be appropriate, and assessing other lessons learned from implementation of COVID-19-related enforcement policies for certain device types.

During the COVID-19 PHE, FDA issued certain enforcement policies for non-invasive remote monitoring devices and clinical electronic thermometers. The policies regarding the modification of previously FDA-cleared clinical electronic thermometers within product code FLL were originally included in FDA's guidance "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" first issued in March 2020, and subsequently revised in June 2020, October 2020, and March 2023.[3] The policies regarding the distribution and use of clinical electronic thermometers not previously cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) ("510(k)-cleared") were outlined in FDA's guidance "Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" issued in April 2020 and revised in March 2023. FDA has revised and consolidated the policies that apply to clinical electronic thermometers in this guidance.

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 FD&C Act and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. 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 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

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[2] Fever is a common symptom of COVID-19, typically appearing 2-14 days after exposure. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

[3] See FDA's guidance "Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring" issued on October 19, 2023, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring. Product code FLL is not within the scope of that guidance.

the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

The enforcement policies in this guidance apply to clinical electronic thermometers, which are regulated as Class II devices under 21 CFR 880.2910, product code FLL. These devices include both contact and non-contact clinical electronic thermometers.

III. Policy

A. Overview

Manufacturers of clinical electronic thermometers are required to submit a premarket notification under section 510(k) of the FD&C Act to FDA and receive FDA clearance prior to marketing these devices in the United States, as well as comply with post-marketing and other requirements. Based on our experience during the COVID-19 pandemic and other available information, in conjunction with the issuance of this guidance, FDA is proposing to exempt certain clinical electronic thermometers—specifically clinical thermometers without telethermography or continuous temperature measurement functions—from premarket notification requirements under section 510(m) of the FD&C Act.[4] At this time, FDA does not propose exempting these devices from other statutory and regulatory requirements. As such, the sections below (organized by clinical thermometer type) describe enforcement policies that are intended to help foster compliance with certain applicable legal requirements for these devices. FDA intends to withdraw this guidance after any final exemption notice has been published in the Federal Register.

To address any unique considerations or other issues not otherwise discussed in this guidance, manufacturers may wish to initiate discussions with the Agency through the Q-Submission Program.[5]

As always, FDA will make case-by-case decisions regarding the enforcement of legal requirements in response to particular circumstances and questions that arise regarding a specific device or device type.

[4] See Federal Register notice "Medical Devices; Exemptions from Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments" (88 FR 75602), available at https://www.federalregister.gov/d/2023-24290

[5] See FDA's guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

(1) Clinical Electronic Thermometers without Telethermography or Continuous Temperature Measurement Functions

a. Devices that were previously 510(k)-cleared

At this time, for clinical electronic thermometers without telethermography or continuous temperature measurement functions that were previously 510(k)-cleared, FDA does not intend to object to the distribution and use of such devices where they have undergone limited modifications to the indications, functionality, or hardware or software without prior submission of a premarket notification under section 510(k) of the FD&C Act,[6] where such submission would be required[7] and where the modifications do not create an undue risk. Similar to the previous policies for these devices, this enforcement policy does not apply to all other statutory and regulatory requirements.

Examples of such modifications that FDA generally believes do not create an undue risk include:

- For devices previously marketed only for use in hospitals or other healthcare facilities, a change to the indications regarding use in the home setting; and
- Hardware or software changes to allow for increased remote monitoring capability.

FDA believes such devices generally will not create such an undue risk where the device incorporates certain performance and labeling elements, such as those described in Section III.B.

b. Devices that were not previously 510(k)-cleared

For clinical electronic thermometers without telethermography or continuous temperature measurement functions that were not previously 510(k)-cleared, FDA does not intend to object to the distribution and use of such devices without prior submission of a 510(k) where such device does not create an undue risk. FDA believes such devices generally will not create such an undue risk where the device incorporates certain performance and labeling elements, such as those described in Section III.B.[8]

Further, for such devices that are already distributed by the date of issuance of this guidance, FDA does not intend to object to such devices not complying with reports of corrections and removals requirements (see 21 CFR Part 806), registration and listing requirements (see 21 CFR Part 807), and Unique Device Identification (UDI) requirements (see 21 CFR Part 801 Subpart B

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[6] As discussed above, in conjunction with the issuance of this guidance, FDA is proposing to exempt clinical electronic thermometers without telethermography or continuous temperature measurement functions from premarket notification requirements under section 510(m) of the FD&C Act. FDA intends to withdraw this guidance after any final exemption notice has been published in the Federal Register.

[7] See 21 CFR 807.81. For further guidance on modifications that trigger the requirement that a manufacturer submit a new 510(k) to FDA, refer to the FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

[8] As discussed above, in conjunction with the issuance of this guidance, FDA is proposing to exempt clinical electronic thermometers without telethermography or continuous temperature measurement functions from premarket notification requirements under section 510(m) of the FD&C Act. FDA intends to withdraw this guidance after any final exemption notice has been published in the Federal Register.

and Part 830) for 180 days from the date of issuance of this guidance. FDA believes that this 180-day transition period, following the issuance of this guidance, will help foster compliance with certain applicable legal requirements, which were also included in FDA's previous enforcement policies for these devices. By the end of the 180-day transition period, if not already doing so, manufacturers of clinical electronic thermometers without telethermography or continuous temperature measurement functions that were not previously 510(k)-cleared are expected to follow these requirements. This aspect of the policy does not apply after the 180-day transition period ends and does not apply to devices that were not distributed prior to the issuance date of this guidance.

(2) Clinical Electronic Thermometers with Telethermography or Continuous Temperature Measurement Functions

a. Devices that were previously 510(k)-cleared

For clinical electronic thermometers with telethermography or continuous temperature measurement functions that are already distributed by the date of issuance of this guidance and were previously 510(k)-cleared, and for which limited modifications to the indications, functionality, or hardware or software were made to allow use in the home setting or for increased remote monitoring capability, FDA does not intend to object to continued distribution and use of such devices without prior submission of a 510(k) where (1) a required premarket notification[9] has been submitted to and accepted by FDA within 180 days from the date of issuance of this guidance, (2) FDA has not taken a final action[10] on the premarket notification, and (3) such devices will not create an undue risk. FDA believes such devices generally will not create such an undue risk where the device incorporates certain performance and labeling elements, such as those described in Section III.B.

In addition, for these same devices, during this 180-day transition period and while the device is under FDA review, FDA does not intend to object to the devices not complying with certain UDI requirements (see 21 CFR Part 801 Subpart B) and other applicable labeling requirements (see 21 CFR Part 801). This enforcement policy does not apply to all other statutory and regulatory requirements. This enforcement policy also does not apply after FDA has taken a final action on the premarket notification for a device.

Once FDA has taken a final action, FDA expects manufacturers to comply with all applicable legal requirements for the device/manufacturer. Following the device's marketing authorization,

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[9] See 21 CFR 807.81. For further guidance on modifications that trigger the requirement that a manufacturer submit a new 510(k) to FDA, refer to the FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

[10] For purposes of this guidance, FDA uses the term "final action" to mean a Medical Device User Fee Amendments (MDUFA) decision, which can include positive decisions, negative decisions, and notices of withdrawals, consistent with the guidance "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals.

this includes labeling updates (see 21 CFR Part 801), compliance with UDI requirements (see 21 CFR Part 801 Subpart B and Part 830), and any applicable updates to registration and listing information, including the submission number (see 21 CFR Part 807 Subparts B-D).

For modified devices under this policy, that are subject to a premarket notification under section 510(k) of the FD&C Act, any required premarket notification is expected to be submitted to and accepted by FDA by the end of the 180-day transition period if the manufacturer intends to continue distribution of the device. FDA believes that a 180-day transition period following issuance of this guidance will help foster compliance with certain applicable legal requirements, including premarket notification requirements.

b. Devices that were not previously 510(k)-cleared

For clinical electronic thermometers with telethermography or continuous temperature measurement functions that are already distributed by the date of issuance of this guidance and were not previously 510(k)-cleared, FDA does not intend to object to continued distribution and use of such devices without prior submission of a 510(k) where (1) a required premarket notification has been submitted to and accepted by FDA within 180 days from the date of issuance of this guidance, (2) FDA has not taken a final action[11] on the premarket notification, and (3) such devices will not create an undue risk. FDA believes such devices generally will not create such an undue risk where the device incorporates certain performance and labeling elements, such as those described in Section III.B.

Further, for these same devices, during the 180-day transition period and while the device is under FDA review, FDA does not intend to object to such devices not complying with reports of corrections and removals requirements (see 21 CFR Part 806), registration and listing requirements (see 21 CFR Part 807), UDI requirements (see 21 CFR Part 801 Subpart B and Part 830), and other applicable labeling requirements (see 21 CFR Part 801). This enforcement policy does not apply to devices that were not distributed prior to the issuance date of this guidance or after FDA has taken a final action on the premarket notification for a device.

Once FDA has taken a final action, FDA expects manufacturers to comply with all applicable legal requirements for the device/manufacturer. Following the device's marketing authorization, this includes labeling updates (see 21 CFR Part 801), compliance with UDI requirements (see 21 CFR Part 801 Subpart B and Part 830), and any applicable updates to registration and listing information, including the submission number (see 21 CFR Part 807 Subparts B-D).

For devices under this policy, any required premarket notification is expected to be submitted to and accepted by FDA by the end of the 180-day transition period if the manufacturer intends to continue distribution of the device. FDA believes that a 180-day transition period following issuance of this guidance will help foster compliance with certain applicable legal requirements, including premarket notification requirements.

[11] For purposes of this guidance, FDA uses the term "final action" to mean a Medical Device User Fee Amendments (MDUFA) decision, which can include positive decisions, negative decisions, and notices of withdrawals, consistent with the guidance "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals.

(3) Disposition of a Device

For manufacturers of devices that intend to discontinue distribution of a device within the scope of this guidance or voluntarily withdraw such devices from the market after the 180-day transition period, as applicable, FDA strongly encourages manufacturers to engage with the Agency if they have questions specific to their situation. To address any unique considerations or other extenuating circumstances, including disposition and use of already distributed[12] devices, not otherwise discussed in this guidance, manufacturers may engage in discussions with the Agency through the Q-Submission Program.[13]

B. Performance and Labeling

As discussed above, FDA believes these devices generally will not create an undue risk where the device incorporates certain performance and labeling elements, such as the following:

1) The device is manufactured consistent with 21 CFR Part 820;[14]

2) The device has marketing authorization through a premarket notification or in one of the following regulatory jurisdictions: European CE Mark, Australian Register of Therapeutic Goods Certificate of Inclusion, Health Canada License, or Ninsho certification in Japan, **or** the performance of the device conforms to the following standards, as applicable:

   - Thermometer Standards
     - ASTM E1104 *Standard Specification for Clinical Thermometer Probe Covers and Sheaths*
     - ASTM E1965 *Standard Specification for Infrared Thermometers for Intermittent*

[12] For purposes of this guidance, devices are considered to be "already distributed" if they are finished devices (21 CFR 820.3(*l*)) that are labeled and are in distribution (21 CFR 807.3(b)) in the U.S. supply chain or are in the possession of the end user. For purposes of this guidance, FDA would generally consider devices to be "in distribution" to mean those finished, labeled devices that are no longer in the manufacturer's possession that are in transit to or held in a third party's device inventory not on behalf of the manufacturer, in a federal, state, or other government stockpile, or at a location where devices are then offered for direct sale to the end user.

[13] See FDA's guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

[14] On February 23, 2022, FDA proposed to amend the device Quality System regulation, 21 CFR part 820, to align more closely with international consensus standards for devices (87 FR 10119; available at https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments). Specifically, FDA proposed to withdraw the majority of the current requirements in part 820 and instead incorporate by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems for regulatory purposes, in part 820. As stated in that proposed rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the current part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. FDA intends to finalize this proposed rule expeditiously. When a final rule takes effect, FDA also intends to update the references to provisions in 21 CFR part 820 in this guidance to be consistent with that rule.

Determination of Patient Temperature
- ASTM E1112 *Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature*
- ISO 80601-2-56 *Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

- Electrical Standards
  - ANSI/AAMI ES60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
  - ANSI/AAMI/IEC 60601-1-2 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
  - ANSI/AAMI/IEC 60601-1-11 *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment*

- Software Standards
  - ANSI/AAMI/IEC 62304 *Medical device software - Software life cycle processes*

- Biocompatibility Standards
  - ANSI/AAMI/ISO 10993-1 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[15] 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."[16]

3) The device labeling includes a clear description of the available data on the device's indications or functions including:
   a. device performance;
   b. method of determining temperature;
   c. potential risks; and
   d. cleaning and reprocessing instructions.

In addition, modifications to hardware or software intended to increase remote monitoring capability may impact cybersecurity risks. Effective cybersecurity is necessary to ensure device safety and functionality. Manufacturers must meet cybersecurity requirements and should refer

[15] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

to FDA's existing policies applicable to their devices. The following online resources may be helpful in developing and maintaining these cybersecurity controls:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Guidance for Industry and Food and Drug Administration Staff;[17]
- Postmarket Management of Cybersecurity in Medical Devices – Guidance for Industry and Food and Drug Administration Staff;[18] and
- FDA Fact Sheet: The FDA's Role in Medical Device Cybersecurity - Dispelling Myths and Understanding Facts.[19]

C. Additional Helpful Resources

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

- Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers [20]
- Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff [21]
- Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff [22]
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff [23]
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff [24]

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions
[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices
[19] https://www.fda.gov/media/123052/download
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-notification-510k-submissions-clinical-electronic-thermometers
[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff
[22] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices
[23] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling
[24] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and