

Contains Nonbinding Recommendations

Enforcement Policy for Clinical Electronic Thermometers 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 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>) and 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 20021 and complete title of the guidance in the request.

Questions

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

Table of Contents

I.	Introduction.....	1
II.	Background.....	2
III.	Scope.....	2
IV.	Policy	3
	A. Overview	3
	B. Performance and Labeling	3
	C. Additional Helpful Resources	5

Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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. 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 clinical electronic thermometers to address this public health emergency.

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 Service (PHS) Act.

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

Contains Nonbinding Recommendations

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 "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

Fever is a common symptom of COVID-19, typically appearing 2-14 days after exposure.³ Therefore clinical electronic thermometers are an important screening and diagnostic tool to assist in the identification of those individuals who may be infected with COVID-19. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability of clinical electronic thermometers during this public health emergency, thereby helping to prevent or alleviate potential shortages as the demand increases due to usage at critical locations such as airports, hospitals, and other locations where groups of individuals may have been exposed.

For current policies regarding the modification of previously FDA-cleared clinical electronic thermometers within product code FLL, please see 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](#)."⁴

III. Scope

The enforcement policy in this guidance applies to clinical electronic thermometers, which are regulated as Class II devices under 21 CFR 880.2910, product code FLL. These devices include both

¹ Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.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/>.

³ <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>

Contains Nonbinding Recommendations

contact and non-contact clinical electronic thermometers.

IV. Policy

A. Overview

In the context of the COVID-19 public health emergency, it is necessary to maintain an adequate supply of clinical electronic thermometers, which are used to measure and monitor the body temperature of patients. 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 requirements.

However, to help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the public health emergency, FDA does not intend to object to the distribution and use of clinical electronic thermometers that are not currently 510(k) cleared 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, Reports of Corrections and Removals requirements in 21 CFR 806, Registration and Listing requirements in 21 CFR Part 807, and Unique Device Identification (UDI) requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA believes such devices will not create such an undue risk where the performance and labeling elements in Section IV.B are met. This policy does not apply to previously 510(k)-cleared clinical thermometers.

B. Performance and Labeling

This section provides recommendations regarding the minimum performance and labeling relevant to the enforcement policy set forth above. FDA encourages firms to discuss any alternatives to these recommendations with FDA (CDRH-COVID19-Thermometers@fda.hhs.gov). FDA believes such devices will not create such an undue risk when the following circumstances are present:

- 1) The device is manufactured consistent with 21 CFR Part 820, ISO 13485:2016 *Medical devices – Quality management systems – Requirements for regulatory purposes*, or equivalent quality system approach;
- 2) The device has marketing authorization in another regulatory jurisdiction (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 E1104-98 (Reapproved 2016) *Standard Specification for Clinical Thermometer Probe Covers and Sheaths*
 - ASTM E1965-98 (Reapproved 2016) *Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature*

Contains Nonbinding Recommendations

- ASTM E1112-00 (Reapproved 2011) *Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature*
 - ISO 80601-2-56 Second edition 2017-03 *Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement [Including: Amendment 1 (2018)].*
 - ASTM E825-98 (Reapproved 2016) *Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature*
 - ASTM E1061-01 (Reapproved 2014) *Standard Specification for Direct-Reading Liquid Crystal Forehead Thermometers*
- Electrical Standards
 - 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*
 - ANSI/AAMI/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 equipment and medical electrical systems used in the home healthcare environment*
 - Software Standards
 - ANSI/AAMI/IEC 62304: 2006/A1:2016 *Medical device software - Software life cycle processes [Including Amendment 1 (2016)]*
 - Biocompatibility Standards
 - ANSI/AAMI/ISO 10993-1 - *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
- 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.
- 4) The device labeling includes a clear identification that the device is not FDA approved or cleared.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA](#)

Contains Nonbinding Recommendations

[Recognized Consensus Standards Database](#).⁵ 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](#).”⁶

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](#)⁷
- [Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff](#)⁸
- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](#)⁹
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Guidance for Industry and Food and Drug Administration Staff](#)¹⁰
- [Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration](#)¹¹
- [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](#)¹²

⁵ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-notification-510k-submissions-clinical-electronic-thermometers>

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>

⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>

¹⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

¹¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling>.

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>.