21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Requirements; Unique Device Identification.	0910–0485
806	Medical Devices; Reports of Corrections and Removals	0910–0359
807, subparts A through D	Medical Device Registration and Listing	0910–0625
820	Current Good Manufacturing Practice, Quality Systems	0910–0073

Dated: October 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24291 Filed 11–2–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4372]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has identified certain class II clinical electronic thermometers that, when finalized, will be exempt from premarket notification requirements, subject to certain limitations. FDA is publishing this notice of that determination and requesting public comment in accordance with the procedures established by the 21st Century Cures Act. FDA will review any comments submitted within the 60-day comment period and will consider whether any modifications should be made to the exemption for certain clinical electronic thermometers prior to publication of its final determination in the **Federal Register**.

DATES: Either electronic or written comments on the notice must be submitted by January 2, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 2, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions*): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–4372 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Clinical Electronic Thermometers; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Center for Devices and Radiological Health, Food

and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993, 301–796–5837, *Madhusoodana.Nambiar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94–295), and the amendments of the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, part 807 of Title 21 of the Code of Federal Regulations (CFR), require persons who intend to market a new device to submit a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires FDA to publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice published under section 510(m)(1)(A) of the FD&C Act.

FDA published the initial notice within the 90-day time frame in the **Federal Register** of March 14, 2017 (82 FR 13609) and issued its final determination of exemption of the devices in such notice in accordance with section 510(m)(1)(B) of the FD&C Act in the **Federal Register** of July 11, 2017 (82 FR 31976). FDA is publishing this notice and requesting public comment in accordance with section 510(m)(1)(A) of the FD&C Act. In a future final action, and after considering comments, FDA intends to amend the codified language in the clinical electronic thermometer regulation to reflect the final determination with respect to exemption.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Limitations on Exemptions

FDA has determined that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness for certain class II clinical electronic thermometers subject to the limitations outlined in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's proposal to grant an exemption from premarket notification applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. After comment and issuance of a notice announcing FDA's final determination, a manufacturer of a clinical electronic thermometer would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in § 880.9 (21 CFR 880.9).

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when the initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices within a generic type of device. In such situations where a partial limitation of the exemption has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for devices that fall outside of the limitations. In table 1, for example, FDA is listing the proposed exemption of clinical electronic thermometers but limits the exemption

to devices that are appropriately tested in accordance with specific FDA-recognized standards (as outlined in the limitations) and excludes clinical electronic thermometers with telethermographic and continuous temperature measurement functions.

Most contact and non-contact clinical electronic thermometers that are appropriately tested in accordance with specific FDA-recognized standards are well-understood devices; however, FDA considers premarket notification requirements for clinical thermometers with telethermographic and continuous temperature measurement functions to be necessary to provide a reasonable assurance of safety and effectiveness because such thermometers include newer technology that may require additional testing beyond that specified in FDA-recognized standards and have additional biocompatibility, interoperability, electromagnetic compatibility, electrical safety, and sterility considerations compared to clinical electronic thermometers without these types of functions.

IV. Class II Device

FDA is identifying the following class II device that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in § 880.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device description	Product code	Partial exemption limitation
880.2910	Clinical electronic thermometer	FLL	Exemption is limited to the following: 1. Device is not a clinical thermometer with telethermography functions; 2. Device is not a clinical thermometer with continuous temperature measurement functions; and 3. Appropriate analysis and testing (such as outlined in the currently FDA-recognized editions of *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,* or *ASTM E1965 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature,* or *ASTM E1112 Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature,* or *ASTM E1104 Standard Specification for Clinical Thermometer Probe Covers and Sheaths*) must validate specifications and performance of the device.

FDA will assign new product codes to clinical electronic thermometers with telethermography functions and those with continuous temperature measurement functions in order to ensure that these devices can be identified distinctly from devices that will be exempt subject to the partial limitations under the existing product code (*i.e.,* exempt and non-exempt devices within a device type will have different product codes).

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Dated: October 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–24290 Filed 11–2–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Standardized Work Plan Form for Use With Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 4, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Standardized Work Plan (SWP) Form for Use with Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension

Abstract: HRSA's BHW requires applicants for training and research grants and cooperative agreements to submit work plans via the SWP form.