under the section heading ''Paragraph 5000 Class D Airspace.'', revise the airspace heading for Jupiter, FL to read ''ASO FL D Jupiter, FL [Amended]''.

Issued in College Park, Georgia, on June 11, 2025.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2025–11200 Filed 6–17–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2023–N–4372]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final Order.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is publishing an order setting forth the Agency's final determination to exempt certain class II clinical electronic thermometers from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for such class II clinical electronic thermometers. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulations. FDA is amending the classification language within the Code of Federal Regulations for certain class II clinical electronic thermometers to reflect this final determination. FDA is publishing this order in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This order is effective June 18, 2025.

FOR FURTHER INFORMATION CONTACT: Linh Lo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993, 301–796–0463, *Linh.Lo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807, subpart E (21 CFR part 807, subpart E), persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a premarket notification to FDA. The device may not be marketed until FDA finds it ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) 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) of the FD&C Act requires that within 90 days of the date of enactment of the Cures Act, and at least once every 5 years thereafter (as FDA determines appropriate), FDA 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 must provide at least a 60-day comment period for any such notice prior to issuing a final determination with respect to the devices contained in the list. Additionally, section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA must publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and provide a 60-day comment period.

In the **Federal Register** of November 3, 2023 (88 FR 75602), FDA published a notice announcing its intent to exempt certain class II clinical electronic thermometers from premarket notification (510(k)) requirements, subject to certain limitations, and provided 60 days for interested persons to submit comments by January 2, 2024. Although FDA received no comments to the docket following a 60-day comment period, FDA is making minor modifications to clarify the limitations on exemption (see section III. B. *Partial Limitations of Exemptions*). Additionally, we provide examples to help clarify the first two partial limitations of exemption (see section III. B. *Partial Limitations of Exemptions*). This final order sets forth our final determination to exempt certain class II clinical electronic thermometers that were the subject of the notice. Through this action, FDA is now amending the language for the identified classification regulation (21 CFR 880.2910(b)) to reflect this final determination.[1]

This final order is expected to result in decreased regulatory burdens and is considered an E.O. 14192 deregulatory action.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a premarket notification (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'') (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff*). 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.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

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

The exemption from premarket notification established in this order applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type (see § 880.9 (21 CFR 880.9)). A manufacturer of a clinical electronic thermometer that otherwise meets the exemption described in 21 CFR 880.2910(b) 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.

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 Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance 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.

As described in table 1, FDA is limiting the exemption for clinical electronic thermometers to devices that have validated specifications and performance via appropriate testing and analysis, such as analysis and testing in accordance with FDA-recognized editions of standards as appropriate. We added ''as appropriate'' to the third limitation in the codified language because a combination of standards may be necessary to fully assess the device. We recommend that manufacturers use the recognized consensus standards database for medical devices (available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/Search.cfm*) to determine the FDA-recognized standards and versions appropriate to their device by searching for the relevant product code.

This order also excludes clinical electronic thermometers with telethermographic functions and continuous temperature measurement functions from the exemption from premarket notification. Examples of clinical electronic thermometers with telethermographic functions include a kiosk with integrated infrared thermometer, a stationary infrared thermometer affixed to a wall or ceiling, or a wheeled cart with integrated infrared thermometry function. Examples of thermometers with continuous temperature measurement functions include temperature probes intended to monitor body temperature during surgical procedures, temperature probes affixed to the skin of neonates or infants intended to monitor body temperature, thermometer patches affixed to the patient's skin, or thermometers that are swallowed to monitor a patient's body temperature. FDA considers premarket notification requirements for infrared clinical electronic thermometers with telethermographic functions and clinical electronic thermometers with 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. For example, an infrared thermometer kiosk is used as a stationary device, has a camera that captures a person's face, and uses a single infrared sensor. These technological characteristics necessitate additional testing beyond those specified in FDA-recognized standards to provide a reasonable assurance of safety and effectiveness.

IV. Class II Device

FDA is identifying the following class II device that will 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 and any partial exemption limitations identified in Table 1.

TABLE 1—CLASS II DEVICES

21 CFR section	Device description	Exempt product code	Non-exempt product code	Partial exemption limitation (as applicable)
880.2910	Clinical Electronic Thermometer.	SDV	Not applicable	Exemption is limited to the following: 1. Device is not a clinical thermometer with telethermographic functions; 2. Device is not a clinical thermometer with continuous temperature measurement functions; and 3. Appropriate analysis and testing (such as that outlined in the currently FDA-recognized editions, as appropriate, 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.

To reduce administrative burden, FDA has assigned new product codes to clinical thermometers with telethermographic functions, product code SDW, and to the exempt clinical electronic thermometers, product code

SDV. New product code SDW, which represents clinical electronic thermometers with telethermographic functions, has been named ''Stationary Infrared Thermometer.'' Clinical electronic thermometers with continuous temperature measurement functions continue to fall under product code FLL. As such, FDA has revised the name of product code FLL from ''Thermometer, Electronic, Clinical'' to ''Continuous Measurement Thermometer'' to more accurately reflect the devices that fall within this product code. New product code SDV, which represents the class II exempt clinical electronic thermometers and reflects the partial exemption limitations, has been named ''Clinical Electronic Thermometer.'' This ensures that the non-exempt devices can be identified distinctly from devices that fall within the partial exemption limitation (*i.e.,* exempt and non-exempt devices have distinct product codes).

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final order contains no new collection of information. This final order refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 800, 801, and 830, regarding labeling have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820 regarding quality system regulation have been approved under OMB control number 0910–0073.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. In § 880.2910, revise paragraph (b) to read as follows:

§ 880.2910 Clinical electronic thermometer.

* * * * *

(b) *Classification.* Class II (performance standards). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter, subject to the limitations in § 880.9 and the following conditions for exemption:

(1) Device is not a clinical thermometer with telethermographic functions;

(2) Device is not a clinical thermometer with continuous temperature measurement functions; and

(3) Appropriate analysis and testing (such as that outlined in the currently FDA-recognized editions, as appropriate, 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.

Dated: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11207 Filed 6–17–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–0427]

RIN 1625–AA00

Safety Zone; Monongahela River MM 122–122.5, Rivesville, WV

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Monongahela River on June 28, 2025, from mile marker 122 to mile marker 122.5, to provide for the safety of life on the navigable waters during a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Pittsburgh, or a designated representative.

DATES: This rule is effective on June 28, 2025, from 9 p.m. through 11 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2025–0427 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Petty Officer Brett Lanzel, MSU Pittsburgh, U.S. Coast Guard; telephone 206–815–6624, email *Brett.J.Lanzel@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this