DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2023–N–0091]

Medical Devices; Cardiovascular Devices; Classification of the Software for Optical Camera-Based Measurement of Pulse Rate, Heart Rate, Breathing Rate, and/or Respiratory Rate

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 31, 2023. The classification was applicable on March 26, 2021.

FOR FURTHER INFORMATION CONTACT: Robert Kazmierski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2319, Silver Spring, MD 20993–0002, 301–796–5447, *Robert.Kazmierski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 27, 2020, FDA received Oxehealth Limited's request for De Novo classification of the Oxehealth Vital Signs. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 26, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.2785.[1] We have named the generic type of device software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate, and it is identified as a device that uses software algorithms to analyze video signal and estimate pulse rate, heart rate, breathing

[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.

rate, and/or respiratory rate. This device is not intended to independently direct therapy.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—SOFTWARE FOR OPTICAL CAMERA-BASED MEASUREMENT OF PULSE RATE, HEART RATE, BREATHING RATE, AND/OR RESPIRATORY RATE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error.	Software verification, validation, and hazard analysis; Cybersecurity assessment; Clinical data; and Labeling.
Delayed or incorrect treatment due to user misinterpretation	Human factors assessment, and Labeling.
Delayed or incorrect treatment due to non-device components failing to provide inputs for software to adequately analyze.	Software verification, validation, and hazard analysis; Clinical data; Human factors assessment; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo Classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; 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 part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.2785 to subpart C to read as follows:

§ 870.2785 Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate.

(a) *Identification.* The device uses software algorithms to analyze video signal and estimate pulse rate, heart rate, breathing rate, and/or respiratory rate. This device is not intended to independently direct therapy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) If required image acquisition hardware is not included with the device, full specifications of the hardware requirements and testing to demonstrate the specified hardware ensures adequate data for validated and accurate measurements;

(iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;

(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy; and

(v) Software documentation must include a cybersecurity vulnerability and management process to assure software functionality.

(2) Clinical data must be provided. This assessment must fulfill the following:

(i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.

(ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iii) The assessment must compare device output with a clinically accurate patient-contacting relevant comparator device in an accurate and reproducible manner.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of improper measurement.

(4) Labeling must include:

(i) A description of what the device measures and outputs to the user;

(ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (garment types/textures, motion, etc.) that may impact measurement results;

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) The expected performance of the device for all intended use populations and environments; and

(v) Robust instructions to ensure correct system setup.

Dated: January 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01967 Filed 1–30–23; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0070]

RIN 1625–AA00

Safety Zone; Laguna Madre, South Padre Island, TX

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters in the Laguna Madre. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a firework display launched from a barge in the Laguna Madre, South Padre Island, Texas. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Corpus Christi or a designated representative.

DATES: This rule is effective from 8:30 through 9 p.m. on January 28, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Anthony Garofalo, Sector Corpus Christi Waterways Management Division, U.S. Coast Guard; telephone 361–939–5130, email *CCWaterways@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 without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This 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.'' Under 5 U.S.C. 553(b)(B), 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 safety zone immediately to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks display and lack sufficient time to provide a reasonable comment period and then to consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with fireworks launched from a barge in the waters of the Laguna Madre.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Corpus Christi (COTP) has determined that potential hazards associated with the fireworks display from 8:30 through 9 p.m. on January 28, 2023, will be a safety concern for anyone within the waters of the Laguna Madre area with a 200 yds radius from the following point; 26°5′49.71″ N, 97°10′14.69″ W. The purpose of this rule is to ensure safety of vessels and persons on these navigable waters in the safety zone while the display of the fireworks takes place in the Laguna Madre.

IV. Discussion of the Rule

This rule establishes a temporary safety zone from 8:30 through 9 p.m. on January 28, 2023. The safety zone will encompass certain navigable waters of the Laguna Madre and is defined by a 200 yds radius around the launching platform. The regulated area encompasses a 200 yds radius from the following point; 26°5′49.71″ N, 97°10′14.69″ W. The fireworks display will take place in waters of the Laguna Madre. No vessel or person is permitted to enter the temporary safety zone during the effective period without obtaining permission from the COTP or a designated representative, who may be contacted on Channel 16 VHF–FM (156.8 MHz) or by telephone at 361–939–0450. The Coast Guard will issue Broadcast Notices to Mariners, Local Notices to Mariners, and/or Safety Marine Information Broadcasts as appropriate.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the safety zone. The temporary safety zone will be enforced for a short period of less than one hour. The zone is limited to a 200 yds radius from the launching position of in the navigable waters of the Laguna Madre. The rule does not completely restrict the traffic within a waterway and allows mariners to request permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person