(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Except for those engines identified in paragraph (g)(2) of this AD, borescope inspect the LPC R1 for damage and cracks at the locations in paragraph (g)(1)(iv) of this AD as follows:

(i) For engines that have accumulated fewer than 300 flight cycles since new (CSN), inspect within 50 flight cycles from September 26, 2019 (the effective date of AD 2019–19–11).

(ii) For engines that have accumulated fewer than 300 flight cycles since installation of v2.11.7 or v2.11.8 electronic engine control (EEC) software, inspect within 50 flight cycles from the effective date of this AD.

(iii) Thereafter, at intervals not to exceed 50 flight cycles until the engine accumulates 300 flight CSN or accumulates 300 flight cycles since the installation of v2.11.7 or v2.11.8 EEC software, whichever occurs later, repeat this borescope inspection for damage and cracks at the locations in paragraph (g)(1)(iv) of this AD.

(iv) Perform the borescope inspection required by paragraphs (g)(1)(i) through (iii) of this AD at the following locations:

(A) the blades tips;

(B) the leading edge;

(C) the leading edge fillet to rotor platform radius; and

(D) the airfoil convex side root fillet to rotor platform radius.

(2) For all affected PW model turbofan engines installed as a ''zero time spare,'' except for PW1519G, PW1521GA and PW1919G model turbofan engines, within 15 flight cycles from the effective date of this AD, and thereafter at intervals not to exceed 15 flight cycles until the engine accumulates 300 flight CSN, perform the borescope inspections required by paragraph (g)(1) of this AD.

(3) As the result of the inspections required by paragraphs (g)(1) and (2) of this AD, before further flight, remove and replace the LPC if:

(i) there is damage on an LPC R1 that exceeds serviceable limits; or

(ii) there is any crack in the LPC R1.

Note 1 to paragraph (g): Guidance on determining serviceable limits can be found in PW Service Bulletin (SB) PW1000G–A–72–00–0125–00A–930A–D, Issue No. 002, dated October 22, 2019, and PW SB PW1000G–A–72–00–0075–00B–930A–D, Issue No. 003, dated October 22, 2019.

(h) Definition

For the purpose of this AD, a ''zero time spare'' is an engine that had zero flight hours time-in-service when it was installed on an airplane after the airplane had entered service.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. You may email your request to: *ANE–AD–AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact Kevin M. Clark, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7088; fax: 781–238–7199; email: *kevin.m.clark@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on October 25, 2019.

Karen M. Grant,

Acting Manager, Engine & Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019–23715 Filed 10–25–19; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2019–N–2484]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Continuous Glucose Monitor Data Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the continuous glucose monitor data management system into class I (general controls). We are taking this action because we have determined that classifying the device into class I (general 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, in part by reducing regulatory burdens.

DATES: This order is effective October 29, 2019. The classification was applicable on August 19, 2014.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4545, Silver Spring, MD 20993–0002, 240–402–6357, *ryan.lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the continuous glucose monitor data management system as class I (general 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 reducing regulatory burdens 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 (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 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 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall 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 within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. 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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 22, 2014, DEXCOM, Inc., submitted a request for De Novo classification of the STUDIO on the Cloud Data Management Software. 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 I if general controls are sufficient to 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 I. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 19, 2014, FDA issued an order to the requestor classifying the device into class I. FDA is codifying the classification of the device by adding 21 CFR 862.2120. We have named the generic type of device continuous glucose monitor data management system, and it is identified as an electronic device intended to acquire, process, and correlate retrospective data from a continuous glucose monitoring device. This device is intended to be used by patients or their healthcare providers when determining therapeutic strategies. A continuous glucose monitor data management system is not a drug dose calculator and does not provide treatment recommendations.

FDA has identified the following risks to health associated specifically with this type of device in table 1.

TABLE 1—CONTINUOUS GLUCOSE MONITOR DATA MANAGEMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Device malfunction (*e.g.*, incorrect data analysis, etc.)	General controls, including design controls.

Section 510(l)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(l)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 862.9.

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 refers 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. 3501–3520). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' 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; and the collections of information in 21 CFR part 820, regarding the quality system regulation, including recordkeeping for design controls, have been approved under OMB control number 0910–0073.

List of Subjects in 21 CFR Part 862

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 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. Add § 862.2120 to subpart C to read as follows:

§ 862.2120 Continuous glucose monitor data management system.

(a) *Identification.* A continuous glucose monitor data management system is an electronic device intended to acquire, process, and correlate retrospective data from a continuous glucose monitoring device. This device is intended to be used by patients or their healthcare providers when determining therapeutic strategies. A continuous glucose monitor data management system is not a drug dose calculator and does not provide treatment recommendations.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 862.9.

Dated: October 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23471 Filed 10–28–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2019–0857]

RIN 1625–AA00

Safety Zone; Naval Training Operations, U.S. Naval Magazine Indian Island, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 500-yard radius of Walan Point, Indian Island, WA. This safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards due to naval training operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Puget Sound.

DATES: This rule is effective from 8 a.m. on October 30, 2019, to 4 p.m. on October 31, 2019, and will be subject to enforcement each of these days from 8 a.m. to 4 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2019–0857 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Ellie Wu, Sector Puget Sound Waterways Management Division, U.S. Coast Guard; telephone (206) 217–6051, email *SectorPugetSoundWWM@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 issuing an NPRM is impracticable. The Coast Guard received notification of these naval training operations from the U.S. Navy on October 7, 2019, and we must take action by October 30, 2019, to protect the public from potential hazards implicated by these training operations. Delaying issuance of this temporary final rule to publish an NPRM and consider comments in response to the NPRM is impracticable, because the safety zone must be in place for the operation, which begins on October 30, 2019.

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 impracticable because of the danger associated with these training operations, which may include but is not limited to high-speed maneuvers, simulated attacks, and the firing of blank ammunition. This rule must be effective starting October 30, 2019, to protect vessels, personnel, and the marine environment from potential hazards associated with these training operations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (formerly 33 U.S.C. 1231). The Captain of the Port Puget Sound (COTP) has determined that potential hazards exist with this naval training operation. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone from potential hazards posed by the naval training operation.

IV. Discussion of the Rule

This rule establishes a safety zone regulation from 10 a.m. on October 30, 2019, to 4 p.m. on October 31, 2019. This regulation will only be subject to enforcement for the following 8-hour period each of these 2 days: 8 a.m. to 4 p.m.

The safety zone will cover navigable waters within a 500-yard radius of Walan Point, Indian Island.

The duration of this regulation is intended to protect personnel, vessels, and the marine environment in these navigable waters while naval training operations are taking place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the waterway on the western side of U.S. Naval Magazine Indian Island. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule will allow vessels to seek 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.