

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 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; 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 888

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 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.3090 to subpart D to read as follows:

§ 888.3090 Intraoperative orthopedic strain sensor.

(a) *Identification.* A strain sensor device is an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision making.

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be conducted:

(i) Mechanical testing to evaluate the effect of the device on the mechanical performance of the implant and to characterize the mechanical limits of the components used with the implant; and

(ii) Accuracy and repeatability testing of strain measurements.

(2) Usability testing must evaluate the effect of the device on the performance of the surgical procedure.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must support the sterility and shelf life of the patient-contacting components of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must validate the reprocessing instructions for reusable components of the device.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(8) Labeling must include the following:

(i) A shelf life;

(ii) Instructions for use;

(iii) Reprocessing instructions for any reusable components; and

(iv) A statement that the device is not intended to provide diagnostic information or influence clinical decision making.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2021–0879]

Special Local Regulations; Charleston Parade of Boats, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation for the Charleston Parade of Boats on December 11, 2021. This action is necessary to ensure safety of life on navigable waters of the United States during the Charleston Parade of Boats. During the enforcement period, no person or vessel may enter, transit through, anchor in, or remain within the designated area unless authorized by the Captain of the Port Charleston (COTP) or a designated representative.

DATES: The regulations in 33 CFR 100.704, Table 1 to § 100.704, Item No. 10, will be enforced from 4:00 p.m. until 8:30 p.m. on December 11, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LCDR Chad Ray, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email Chad.L.Ray@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.704, Item No. 10, for the Charleston Parade of Boats from 4:00 p.m. through 8:30 p.m. on December 11, 2021. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Seventh Coast Guard District § 100.704, Item No. 10, specifies the location of the regulated area for the Charleston Parade of Boats, which encompasses a portion of the waterways during the parade transit from Charleston Harbor Anchorage A through Shutes Folly, Bennis Reach, Horse Reach, Hog Island Reach, Town Creek Lower Reach, Ashley River, and finishing at City Marina. During the enforcement period, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period

via the Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

Dated: November 23, 2021.

J.D. Cole,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2021-26202 Filed 12-1-21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2021-0875]

RIN 1625-AA00

Safety Zone; Fireworks Display, Columbia River, Richland, WA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within a 600-foot radius of a fireworks display on the Columbia River for the City of Richland Christmas Fireworks Display in Richland, WA. This action is necessary to provide for the safety of life on these navigable waters during the fireworks display. Entry of vessels or persons, transiting though, mooring, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Sector Columbia River or a designated representative.

DATES: This rule is effective from 7:30 p.m. through 9 p.m. on December 3, 2021, and from 7:30 p.m. through 9 p.m. on December 4, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2021-0875 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 on this rule, call or email LCDR Sean Morrison, Waterways Management Division, Marine Safety Unit Portland, Coast Guard; telephone 503-240-9319, email D13-SMB-MSUPortlandWWM@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. The City of Richland did not alert the Coast Guard of the fireworks display and the associated safety hazards until November 9, 2021. We must establish this safety zone on December 3, 2021 and lack sufficient time to provide a reasonable comment period and then 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 an urgent action is needed to respond to the safety hazards associated with the planned fireworks display on December 3 and 4, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Columbia River has determined that potential hazards associated with the fireworks display on December 3, 2021 and December 4, 2021, will be a safety concern for anyone within a 600-foot radius of the fireworks display. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the fireworks display is taking place.

IV. Discussion of the Rule

This rule establishes a safety zone for the City of Richland Christmas Fireworks Display from 07:30 p.m. through 09 p.m. on December 3, 2021 and from 07:30 p.m. through 09 p.m. on December 4, 2021. The Safety Zone will cover all navigable waters within 600-feet of the pier located on the Columbia River near Howard Amon Park Waterfront on 80 Lee Boulevard,

Richland, WA 99352 at approximate location 46°16'29" N; 119°16'10" W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the fireworks display is taking place. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of the U.S. Coast Guard Sector Columbia River.

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 size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area on the Columbia River for 1.5 hours during two consecutive evenings, when vessel traffic is normally low. Moreover the rule allows 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. 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 safety