

neither an environmental assessment nor an environmental impact statement is required.

### III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. 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 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 801, regarding labeling, have been approved under OMB control number 0910–0485.

### IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. K112711—De Novo Request per 513(f) pursuant to the Agency's NSE Determination, dated November 18, 2011, From Lexicor Medical Technology, LLC, dated December 7, 2011.

### List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

### PART 882—NEUROLOGICAL DEVICES

- 1. The authority citation for 21 CFR part 882 continues to read as follows:

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

- 2. Add § 882.1440 to subpart B to read as follows:

#### § 882.1440 Neuropsychiatric interpretive electroencephalograph assessment aid.

(a) *Identification.* The neuropsychiatric interpretive electroencephalograph assessment aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG

assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

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

(1) The technical parameters of the device, hardware and software, must be fully characterized and must demonstrate a reasonable assurance of safety and effectiveness.

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's condition, must be described in detail in the software requirements specification and software design specification. Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device parts that contact the patient must be demonstrated to be biocompatible.

(3) The device must be designed and tested for electrical safety, electromagnetic compatibility, thermal, and mechanical safety.

(4) Clinical performance testing must demonstrate the accuracy, precision, reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cutoffs).

(5) Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value, and negative predictive value per the device intended use. Repeatability of measurements must be demonstrated using interclass correlation coefficients and illustrated by qualitative scatter plot(s).

(6) The device design must include safeguards to prevent use of the device as a stand-alone diagnostic.

(7) The labeling must include the following information:

(i) A warning that the device is not to be used as a stand-alone diagnostic.

(ii) A detailed summary of the clinical performance testing, including any adverse events and complications.

(iii) The qualifications and training requirements for device users including technicians and clinicians.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians should convey to patients regarding the collection of EEG data.

(vi) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vii) Where appropriate, validated methods and instructions for reprocessing of any reusable components.

Dated: February 12, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–03388 Filed 2–14–14; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 100

[Docket No. USCG–2013–1067]

#### Special Local Regulation; Southern California Annual Marine Events for the San Diego Captain of the Port Zone

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 during the California Half Ironman Triathlon, held on March 29, 2014. This event occurs in Oceanside Harbor, Oceanside, CA. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels of the triathlon, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative.

**DATES:** This rule is effective from 6:40 a.m. to 9:30 a.m. on March 29, 2014.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or email Petty Officer Bryan Gollongly, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7656, email [D11-PF-MarineEventsSanDiego@uscg.mil](mailto:D11-PF-MarineEventsSanDiego@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 in support of the annual marine event, the California Half Ironman Triathlon (Item 2 on Table 1 of 33 CFR 100.1101), held

on the last Saturday morning in March. The Coast Guard will enforce the special local regulations on the Harbor and Federal Channel in Oceanside on March 29, 2014 from 6:40 a.m. to 9:30 a.m. The triathlon course will commence at the Oceanside Harbor boat ramp then proceed outbound through the federal channel to the Oceanside Harbor Entrance, and then proceed back through the channel to the boat ramp.

Under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from entering into, transiting through, or anchoring within this regulated area unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 5 U.S.C. 552(a) and 33 CFR 100.1101. In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this notice, he or she may use a Broadcast Notice to Mariners or other communications coordinated by the event sponsor to grant general permission to enter the regulated area.

Dated: January 13, 2014.

**S.M. Mahoney,**

*Captain, U.S. Coast Guard, Captain of the Port San Diego.*

[FR Doc. 2014-03470 Filed 2-14-14; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2014-0010]

RIN 1625-AA00

#### **Safety Zone: Maintenance Dredging 35-Foot Channel and Rock Removal; Portland Harbor, Portland, ME**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone around the blasting and dredging project taking place in Portland Harbor between Portland and South Portland, Maine. This safety zone is required to protect

users of the waterway from the safety hazards associated with this blasting and dredging project, which is being undertaken to increase the water depth of the main channel to 35 feet. Entry into this safety zone is prohibited unless authorized by the Captain of the Port (COTP) Northern New England.

**DATES:** This rule is effective without actual notice from February 18, 2014 until March 31, 2014. For the purposes of enforcement, actual notice will be used from the date the rule was signed, February 6, 2014, until February 18, 2014.

This rule will be enforced at various dates and times to be determined (TBD) to accommodate dredging and blasting operations, and will be advertised via Local Notice to Mariners and Broadcast Notice to Mariners.

**ADDRESSES:** Documents mentioned in this preamble are part of docket [USCG-2014-0010]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Junior Grade Elizabeth Gunn, U.S. Coast Guard, Sector Northern New England, Waterways Management Division, via telephone at (207) 767-0398 or email at [Elizabeth.V.Gunn@uscg.mil](mailto:Elizabeth.V.Gunn@uscg.mil). If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, via telephone at (202) 366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Table of Acronyms**

DHS Department of Homeland Security  
FR Federal Register

##### **A. Regulatory History and Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 United States Code (USC) 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

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 the Army Corps of Engineers (ACOE) notified the Coast Guard of the blasting operations on January 8, 2014. This notice was not received in sufficient time for the Coast Guard to solicit public comments before the start of blasting operations. Consequently, waiting for a comment period to run before publishing this rule would inhibit the Coast Guard's ability to keep the boating public safe and, thus, would be impracticable and contrary to the public interest. Because blasting and dredging operations must be completed by March 15, 2014, in accordance with Maine Department of Environmental Protection (DEP) permitting, it would not be feasible for the project to be delayed or rescheduled. Immediate action is needed to protect the maritime public from the potential hazards associated with blasting operations, which include the use of explosives below the waterline. This regulation is necessary to ensure the immediate safety of users of the waterway.

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**. For the same reasons discussed in the preceding paragraph, delaying the effective date of this rule would be impracticable and contrary to the public interest.

##### **B. Basis and Purpose**

The legal basis for the temporary rule is 33 USC 1226, 1231, 46 USC Chapter 701, 3306, 3703; 50 USC 191, 195; Pub. L. 107-295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety zones.

As part of the Maintenance Dredging 35-Foot Channel and Rock Removal Project, the Army Corps of Engineers must blast and dredge in portions of the Portland Harbor near Portland and South Portland, Maine. Due to inherent dangers associated with blasting and dredging operations, a safety zone is necessary to help ensure the safety of the maritime public operating near the work site. The potential explosive arc for each blasting site has been calculated to be approximately 600 feet.

The project is also required to comply with applicable state laws.