

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.5898 to subpart F to read as follows:

§ 882.5898 Transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder.

(a) *Identification.* A transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder (ADHD) is a prescription device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead.

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

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

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical, mechanical, and thermal safety of the device.

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

(i) Electrical performance testing must validate electrical output and duration of stimulation;

(ii) Battery performance testing must be performed; and

(iii) Adhesive integrity testing of the electrodes must be conducted.

(4) The technical parameters of the device including waveform, maximum output current and voltage, pulse duration, frequency, net charge per pulse, maximum current density, maximum average current, and maximum average power density must be fully characterized.

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

(6) Shelf life testing of the electrodes must be performed to demonstrate continued package integrity and component functionality over the labeled shelf life.

(7) Labeling must include the following:

(i) A contraindication for patients with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator;

(ii) A warning that the device is only for use on clean, intact skin;

(iii) Information on how the device operates and the typical sensations experienced during treatment;

(iv) A detailed summary of the device technical parameters;

(v) A shelf life for the electrodes;

(vi) Instructions for use, including placement of the device on the patient; and

(vii) Cleaning instructions.

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2021–0866]

Safety Zone; Sacramento New Year's Eve Fireworks, Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the three safety zones in the navigable waters of the Sacramento River near River Walk Park and the Tower Bridge in Sacramento, CA in support of the Sacramento New Year's Eve Fireworks in the Captain of the Port, San Francisco area of responsibility on December 31, 2021. This action is necessary to protect personnel, vessels, and the marine environment from the dangers associated with pyrotechnics. During the enforcement periods noted below, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone, unless authorized by the Patrol Commander (PATCOM) or other federal, state, or local law enforcement agencies on scene to assist the Coast Guard in enforcing the regulated area.

DATES: The regulation in 33 CFR 165.1191, will be enforced for the location in Table 1 to § 165.1191, Item number 25, from 8:30 p.m. until 9:45 p.m. on December 31, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Lieutenant Anthony Solares, Waterways Management, U.S. Coast Guard Sector San Francisco; telephone (415) 399–3585, email SFWaterways@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones established in 33 CFR 165.1191 Table 1,

Item number 25, for the Sacramento New Year's Eve Fireworks Display from 8:30 p.m. until 9:45 p.m. on December 31, 2021, or as announcement via Broadcast Notice to Mariners. The safety zone will extend to all three safety zones established in 33 CFR 165.1191 Table 1, Item number 25. During the period of enforcement, the three safety zones for the Sacramento New Year's Eve Fireworks Display will encompass the navigable waters, from surface to bottom, around the fireworks firing sites within three respective circles each with a radius of 700 feet with the respective circle centers in approximate positions:

Southern Firing Site at 38°34'50.00" N 121°30'29.20" W,

Northern Firing Site at 38°35'02.07" N 121°30'39.73" W, and

Near the Tower Bridge at 34°34'49.43" N 121°30'29.19" W (NAD83).

The safety zones will be enforced from 8:30 p.m. until 9:45 p.m. on December 31, 2021, or as announced via Broadcast Notice to Mariners.

In addition to this notification in the **Federal Register**, the Coast Guard plans to provide notification of the safety zone and its enforcement period via the Local Notice to Mariners.

Under the provisions of 33 CFR 165.1191, unauthorized persons or vessels are prohibited from entering into, transiting through, or anchoring in the safety zone during all applicable effective dates and times, unless authorized to do so by the PATCOM or other Official Patrol defined as a federal, state, or local law enforcement agency on scene to assist the Coast Guard in enforcing the regulated area. Additionally, each person who receives notice of a lawful order or direction issued by the PATCOM or Official Patrol shall obey the order or direction. The PATCOM or Official Patrol may, upon request, allow the transit of commercial vessels through regulated areas when it is safe to do so.

If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, a Broadcast Notice to Mariners may be used to grant general permission to enter the regulated area.

Dated: December 6, 2021.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

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