○ a summary of the expected risks and benefits of using the device;

○ a summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications;

○ information on how the device operates and the typical sensations experienced during treatment;

○ a detailed summary of the device technical parameters;

○ an expiration date/shelf life for the electrodes and the number of times they can be reused; and

○ disposal instructions.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification prior to marketing the device, which contains information about the transcutaneous electrical nerve stimulator to treat headache device they intend to market.

II. 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.

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. K122566 De Novo Petition for the Cefaly Device From STX–Med SPRL, dated December 13, 2012.

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 § 882.5891 to subpart F to read as follows:

§ 882.5891 Transcutaneous electrical nerve stimulator to treat headache.

(a) *Identification.* A transcutaneous electrical nerve stimulator to treat headache is a device used to apply an electrical current to a patient's cranium through electrodes placed on the skin.

(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) Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

(3) The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge (μC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm^2, r.m.s.), maximum average current (mA), maximum average power density (W/cm^2), and the type of impedance monitoring system must be fully characterized.

(4) Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted.

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

(6) Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

(7) Labeling must include the following:

(i) Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.

(ii) Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery.

(iii) Appropriate precautions such as the long-term effects of chronic use of the device are unknown.

(iv) A summary of the expected risks and benefits of using the device.

(v) A summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications.

(vi) Information on how the device operates and the typical sensations experienced during treatment.

(vii) A detailed summary of the device technical parameters.

(viii) An expiration date/shelf life for the electrodes and the number of times they can be reused.

(ix) Disposal instructions.

Dated: June 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15625 Filed 7–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2014–M–0701]

Medical Devices; Physical Medicine Devices; Classification of the Nonpowered Lower Extremity Pressure Wrap

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nonpowered lower extremity pressure

wrap into class I (general controls). The Agency is classifying the device into class I (general controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective August 4, 2014. The classification was applicable on December 18, 2013.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1434, Silver Spring, MD 20993–0002, 301–796–6476, *michael.hoffmann@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on January 7, 2011, classifying the Restless Legs Device, into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On January 23, 2011, Mary M. Sorg dba PJ Sleeper's, submitted a request for classification of the Restless Leg Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class I (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, 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. FDA classifies devices into class I if general controls by themselves are sufficient to provide reasonable assurance of safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class I. FDA believes general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 18, 2013, FDA issued an order to the requester classifying the device into class I. FDA is codifying the classification of the device by adding § 890.5760. The device is assigned the generic name nonpowered lower extremity pressure wrap, and it is identified as a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.

FDA believes that general controls provide reasonable assurance of safety and effectiveness. Nonpowered lower extremity pressure wraps are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. ((21 CFR 882.1440(a)); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and 21 CFR 801.109 (*Prescription devices*).) Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

II. 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.

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 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. Request for automatic Class III designation under (De Novo) 513(f)(2) 510(k)# K102707, from Mary M. Sorg dba PJ Sleeper's, January 23, 2011.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

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

■ 2. Add § 890.5760 to subpart F to read as follows:

§ 890.5760 Nonpowered lower extremity pressure wrap.

(a) *Identification.* A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome.

(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 § 890.9.

Dated: June 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–15626 Filed 7–2–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2014–0360]

Special Local Regulation; Eleventh Coast Guard District Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of Enforcement of Regulation.

SUMMARY: The Coast Guard will enforce the San Diego Maritime Museum Tall Ship Festival of Sail special local regulations during this year's event on August 29, 2014 through September 1, 2014. This event occurs on the navigable waters of the San Diego Bay in San Diego, CA. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels of the boat parade, 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 9 a.m. to 7 p.m. on August 29, 2014 through September 1, 2014.

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

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 in support of San Diego Maritime Museum Tall Ship Festival of Sail (Item 15 on Table 1 of 33 CFR 100.1101), held on a weekend in September. The Coast Guard will enforce the special local regulations on the San Diego Bay in San Diego, CA on Friday August 29, 2014 through Monday September 1, 2014 from 9 a.m. to 7 p.m.

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 the patrol and notification of the regulation.

This document is issued under authority of 5 U.S.C. 552(a) and 33 CFR 100.1101. In addition to this document 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 with the event sponsor to grant general permission to enter the regulated area.

Dated: June 5, 2014.

J.A. Janszen,

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

[FR Doc. 2014–15543 Filed 7–2–14; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0160]

RIN 1625–AA00

Safety Zone; Swim Around Charleston, Charleston, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary moving safety zone during the Swim Around Charleston, a swimming race occurring on waters of the Wando River, the Cooper River, Charleston Harbor, and the Ashley River, in Charleston, South Carolina. The Swim Around Charleston is scheduled to take place on September 21, 2014. The temporary safety zone is necessary for the safety of the swimmers, participant vessels, spectators, and the general public during the event. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule will be effective from 11:30 a.m. until 6:30 p.m. on September 21, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0160. 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 Chief Warrant Officer Christopher Ruleman, Sector Charleston Waterways Management, U.S. Coast Guard; telephone (843) 740–3184, email *christopher.l.ruleman@uscg.mil.* If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: