4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2014-M-0850]

Medical Devices; Neurological Devices; Classification of the Transcranial Magnetic Stimulator for Headache

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the transcranial magnetic stimulator for headache into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the transcranial magnetic stimulator for headache classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on December 13, 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 part 807 (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 (Public Law 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.

On March 1, 2013, Neuralieve (now eNeura Therapeutics LLC), submitted a request for classification of the NEURALIEVE CERENA Transcranial Magnetic Stimulator under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (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). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the 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 II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 13, 2013, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding § 882.5808.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a transcranial magnetic stimulator for headache will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name transcranial magnetic stimulator for headache, and it is identified as a device that delivers brief duration, rapidly alternating, or pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in table 1:

Table 1.--Transcranial Magnetic Stimulator for Headache Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Failure to identify correct population	Clinical testing Labeling
Ineffective treatment	Clinical testing Non-clinical testing Software verification, validation, and hazard analysis Labeling
Risk of seizure	Clinical testing Non-clinical testing Labeling
Scalp discomfort, scalp burn, dizziness, nausea, or other adverse effects	Clinical testing Non-clinical testing Thermal safety Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction	Biocompatibility Labeling
Electrical shock, burn	Electrical equipment safety Thermal safety Labeling
Interference with other electrical equipment	Electromagnetic compatibility Labeling
Noise irritation and hearing loss	Non-clinical testing Labeling

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, and thermal safety.
- Appropriate verification, validation, and hazard analysis must be performed on the device software and firmware.
- The elements of the device that contact the patient must be assessed to be biocompatible.
- Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. This includes full characterization of the magnetic pulse output and resulting magnetic field map. This also includes characterization of the sound level of the device during use.
- Clinical testing must demonstrate that the device is safe and effective for treating headache in the indicated patient population.
- The physician and patient labeling must include the following:
    - A summary of the clinical performance testing, including any adverse events and complications;
    - the intended use population in terms of the types of headaches appropriate for use with the device;
    - information on how to report adverse events and device malfunctions; and
    - a diagram or picture depicting the proper placement of the device on the user.

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) 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 transcranial magnetic stimulator for headache 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. K130556 De Novo Petition for the NEURALIEVE CERENA Transcranial Magnetic Stimulator From Neuralieve, dated March 1, 2013.

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 § 882.5808 to subpart F to read as follows:

§ 882.5808 Transcranial magnetic stimulator for headache.

(a) Identification. A transcranial magnetic stimulator device for headache is a device that delivers brief duration, rapidly alternating, or pulsed, magnetic fields that are externally directed at spatially discrete regions of the brain to induce electrical currents for the treatment of headache.

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

(1) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, and thermal safety.

(2) Appropriate verification, validation, and hazard analysis must be performed on the device software and firmware.

(3) The elements of the device that contact the patient must be assessed to be biocompatible.

(4) Non-clinical testing data must demonstrate that the device performs as intended under anticipated conditions of use. This includes full characterization of the magnetic pulse output and resulting magnetic field map. This also includes characterization of the sound level of the device during use.

(5) Clinical testing must demonstrate that the device is safe and effective for treating headache in the indicated patient population.

(6) The physician and patient labeling must include the following:

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

(ii) The intended use population in terms of the types of headaches appropriate for use with the device.

(iii) Information on how to report adverse events and device malfunctions.

(iv) A diagram or picture depicting the proper placement of the device on the user.

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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