TABLE 1—TRUNK AND LIMB ELECTRICAL STIMULATOR TO TREAT HEADACHE RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Software malfunction leading to injury or discomfort (*e.g.,* tissue damage due to over-stimulation).	Software verification, validation, and hazard analysis.
Hardware malfunction leading to injury or discomfort	Non-clinical performance testing, Shelf life testing, and Labeling.
Use error that may result in user discomfort, injury, or delay treatment for headaches.	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final 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).

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 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; 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; and the collections of information in part 801, regarding labeling, have been

approved under OMB control number 0910–0485.

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 part 882 continues to read as follows:

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

■ 2. Add § 882.5899 to subpart F to read as follows:

§ 882.5899 Trunk and limb electrical stimulator to treat headache.

(a) *Identification.* A trunk and limb electrical stimulator to treat headache is a device intended to treat headache through the application of electrical stimulation anywhere on the body of the patient apart from the patient's head or neck through electrodes placed on the skin. The stimulation may be provided transcutaneously or percutaneously.

(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. This testing must include:

(i) Characterization of the electrical stimulation, including the following: Waveforms; output modes; maximum output voltage and maximum output current (at 500Ω, 2kΩ, and 10kΩ loads); pulse duration; frequency; net charge per pulse; and maximum phase charge, maximum current density, maximum average current, and maximum average power density (at 500Ω);

(ii) Characterization of the impedance monitoring system; and

(iii) Characterization of the electrode performance including the electrical performance, adhesive integrity, shelf-life, reusability, and current distribution of the electrode surface area.

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

(3) Performance testing must demonstrate electromagnetic compatibility and electrical, mechanical, and thermal safety in the intended use environment.

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

(5) Labeling must include the following:

(i) Instructions for use, including the typical sensations experienced during treatment;

(ii) A detailed summary of the electrical stimulation output, and the device technical parameters, including any wireless specifications;

(iii) A shelf life for the electrodes and reuse information; and

(iv) Instructions on care and cleaning of the device.

Dated: November 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26175 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2021–N–0290]

Medical Devices; Neurological Devices; Classification of the Conditioning Tool for Eating Disorders

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the conditioning tool for eating disorders into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the conditioning tool for eating disorders' classification. We are taking this action because we

have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 31, 2011.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 4110, Silver Spring, MD 20993–0002, 301–796–6476, *Michael.Hoffmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the conditioning tool for eating disorders as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21

U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on May 24, 2007, finding the

Mandometer not substantially equivalent to a predicate not subject to premarket approval. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

AB Mando submitted a request for De Novo classification of the Mandometer, dated June 19, 2007. 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.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 31, 2011, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 882.5060.[1] We have named the generic type of device conditioning tool for eating disorders, and it is identified as a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

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

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[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

TABLE 1—CONDITIONING TOOL FOR EATING DISORDERS RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Ineffective treatment leading to worsening condition of the patient, progression of disease, and/or delay of alternative treatments.	Nonclinical performance testing; Software validation, verification and hazard analysis; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Electrical shock or burns	Electrical safety testing, Electromagnetic compatibility (EMC) testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final 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).

At the time of classification, conditioning tools for eating disorders are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

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. 3501–3520). 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 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; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

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 882 is amended as follows:

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, 360*l*, 371.

■ 2. Add § 882.5060 to subpart F to read as follows:

§ 882.5060 Conditioning tool for eating disorders.

(a) *Identification.* A conditioning tool for eating disorders is a prescription device that non-invasively measures the mass of food eaten during a meal and provides feedback in the form of eating rate, patient satiety, and eating pattern information to the patient.

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

(1) Nonclinical performance testing must demonstrate:

(i) Device measurement accuracy and repeatability; and

(ii) Device feedback accuracy.

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

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

(4) Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(5) Labeling and patient labeling must be provided which includes the following:

(i) Information identifying and explaining how to use the device and its components; and

(ii) Information on how the device operates and the typical course of treatment.

Dated: November 26, 2021.

Lauren K. Roth,
Associate Commissioner for Policy.
[FR Doc. 2021–26176 Filed 12–1–21; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2021–N–0648]

Medical Devices; Orthopedic Devices; Classification of the Intraoperative Orthopedic Strain Sensor

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the intraoperative orthopedic strain sensor into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intraoperative orthopedic strain sensor's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 2, 2021. The classification was applicable on March 28, 2019.

FOR FURTHER INFORMATION CONTACT: Colin O'Neill, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4458, Silver Spring, MD 20993–0002, 301–796–6428, *Colin.ONeill@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the intraoperative orthopedic strain sensor as class II (special controls), which we have determined will provide a