



March 26, 2018

Scion NeuroStim, LLC
% Dawn Reilly-O'Dell
Principal Consultant
Full Circle Regulatory Consulting, LLC
107 Casablanca Court
Cary, North Carolina 27519

Re: DEN170023

Trade/Device Name: ThermoNeuroModulation (TNM) Device
Regulation Number: 21 CFR 882.5893
Regulation Name: Thermal vestibular stimulator for headache
Regulatory Class: Class II
Product Code: QAR
Dated: April 14, 2017
Received: April 18, 2017

Dear Dawn Reilly-O'Dell:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the ThermoNeuroModulation Device, TNM Device, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The TNM Device is intended to stimulate the vestibular system using tightly controlled thermal waveforms. The TNM Device is indicated for the prophylactic treatment of episodic migraine in adolescent and adult patients 12 years or older.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the ThermoNeuroModulation Device, and substantially equivalent devices of this generic type, into Class II under the generic name Thermal vestibular stimulator for headache.

FDA identifies this generic type of device as:

Thermal vestibular stimulator for headache. The thermal vestibular stimulator for headache is a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of headache.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law

provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On April 18, 2017, FDA received your De Novo requesting classification of the ThermoNeuroModulation Device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ThermoNeuroModulation Device into class I or II, it is necessary that the proposed class have sufficient regulatory 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 has determined that, for the previously stated indications for use, the ThermoNeuroModulation Device can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risk	Mitigation Method
Adverse tissue reaction	Biocompatibility evaluation Cleaning validation Labeling
Thermal injury	Labeling Non-clinical performance testing Thermal safety testing Technical specifications Software verification, validation, & hazard analysis
Ear tenderness and/or pruritus	Labeling Non-clinical performance testing Thermal safety testing
Nausea and/or dizziness	Labeling Non-clinical performance testing Software verification, validation, & hazard analysis
Tinnitus	Labeling Non-clinical performance testing Software verification, validation, & hazard analysis

In combination with the general controls of the FD&C Act, the thermal vestibular stimulator for headache is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.
2. Performance testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

3. The technical parameters of the device, including waveform outputs and temperature limits, must be identified.
4. Cleaning validation of earpieces must be conducted.
5. Software verification, validation, and hazard analysis must be performed.
6. Labeling must include the following:
 - a. Information on how the device operates and the typical sensations experienced during treatment;
 - b. A detailed summary of the device's technical parameters; and
 - c. Instructions for maintenance and cleaning of the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the thermal vestibular stimulator for headache they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Stacie Gutowski at 240-402-6032.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health