



May 20, 2019

Theranica Bioelectronics Ltd  
% Janice Hogan  
Official Correspondent  
Hogan Lovells US LLP  
1735 Market Street, Floor 23  
Philadelphia, Pennsylvania 19103

Re: DEN180059

Trade/Device Name: Nerivio Migra  
Regulation Number: 21 CFR 882.5899  
Regulation Name: Trunk and limb electrical stimulator to treat headache  
Regulatory Class: Class II  
Product Code: QGT  
Dated: November 6, 2018  
Received: November 6, 2018

Dear Janice Hogan:

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 Nerivio Migra, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Nerivio Migra is indicated for acute treatment of migraine with or without aura in patients 18 years of age or older who do not have chronic migraine. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Nerivio Migra, and substantially equivalent devices of this generic type, into Class II under the generic name trunk and limb electrical stimulator to treat headache.

FDA identifies this generic type of device as:

**Trunk and limb electrical stimulator to treat headache.** 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.

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 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 announcing the classification.

On November 6, 2018, FDA received your De Novo requesting classification of the Nerivio Migra. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Nerivio Migra 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 Nerivio Migra 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:

Table 1 – Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Adverse tissue reaction	Biocompatibility evaluation
Electrical, mechanical, or thermal hazards that may result in user discomfort or injury (e.g., electrical shock or burn)	Non-clinical performance testing Electrical, mechanical, and thermal safety testing Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility (EMC) testing Labeling
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 Labeling
Use error that may result in user discomfort, injury, or delay treatment for headaches	Labeling

In combination with the general controls of the FD&C Act, the trunk and limb electrical stimulator to treat headache is subject to the following special controls:

- 1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. This testing must include:
  - a) 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 500 $\Omega$ );

- b) Characterization of the impedance monitoring system; and
  - c) 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 include the following:
- a) Instructions for use, including the typical sensations experienced during treatment;
  - b) A detailed summary of the electrical stimulation output, and the device technical parameters, including any wireless specifications;
  - c) A shelf life for the electrodes and reuse information; and
  - d) Instructions on care and cleaning of the device.

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

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov).

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 trunk and limb electrical stimulator to treat 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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](mailto: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 Erin Keegan at 240-402-6534.

Sincerely,

Carlos Pena, PhD, MS  
Director  
OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health