



March 06, 2023

Neuromod Devices Limited
% Diarmuid Flavin
COO, Neuromod Devices
The Digital Hob, Unit J, Digital Court Rainford St.
Dublin 8, D08 R2YP
IRL

Re: DEN210033

Trade/Device Name: Lenire

Regulation Number: 21 CFR 874.3410

Regulation Name: Combined acoustic and electrical external stimulation device for the relief of tinnitus

Regulatory Class: Class II

Product Code: QVN

Dated: August 18, 2021

Received: August 18, 2021

Dear Diarmuid Flavin:

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

Lenire is intended to provide bimodal (sound and transmucosal electrical tongue) stimulation to temporarily relieve the symptoms of tinnitus in patients 18 years of age and older suffering from at least moderate (as defined by the Tinnitus Handicap Inventory) tinnitus. The treatment is intended to be self-administered by the patient following prescription by a healthcare professional who is experienced in the evaluation and management of tinnitus.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Lenire, and substantially equivalent devices of this generic type, into Class II under the generic name combined acoustic and electrical external stimulation device for the relief of tinnitus.

FDA identifies this generic type of device as:

Combined acoustic and electrical external stimulation device for the relief of tinnitus. A combined acoustic and electrical external stimulation device for the relief of tinnitus is a device that provides acoustic stimulation in the ear and external, electrical stimulation of sensory nerves to relieve tinnitus.

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 December 21, 2022, FDA received your De Novo requesting classification of the Lenire. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Lenire 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 Lenire 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:

Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation Labeling
Thermal and Electrical safety: Injury from electrical current on skin or mucosa causing one or more of the following: <ul style="list-style-type: none"> • Burn • Irritation • Electrical shock • Pain • Glandular hypersecretion • Headache 	Non-clinical performance testing Clinical performance testing Human factors testing Software verification, validation, and hazard analysis Electrical safety testing Electromagnetic compatibility testing Battery safety testing Labeling
Increase in tinnitus or associated behavior issues during treatment	Clinical performance testing Labeling
Hearing loss from overstimulation	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the combined acoustic and electrical external stimulation device for the relief of tinnitus is subject to the following special controls:

- (1) Clinical performance testing must demonstrate performance as intended under anticipated conditions for use including the following:
 - (i) Evaluation of tinnitus symptoms using a validated method; and
 - (ii) Evaluation of all adverse events.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
 - (i) Verification of specified electrical stimulation parameters; and
 - (ii) Verification of specified acoustic stimulation parameters, including maximum output limits, distortion levels, and frequency response.
- (3) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (6) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use.
- (7) Labeling must include the following:
 - (i) A statement that the device is intended to be prescribed by a healthcare professional with expertise in the evaluation and management of tinnitus;
 - (ii) Information regarding emotional, psychological, and physical considerations for patient selection; and
 - (iii) Device specifications, including the materials of patient-contacting components of the device, electrical output waveform, stimulation peak voltage and current, pulse duration, frequency, maximum current density, maximum phase charge, and power source.

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.

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 combined acoustic and electrical external stimulation device for the relief of tinnitus 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Ting Zhang, Ph.D. at 301-796-1289.

Sincerely,

for Malvina B. Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health