



February 5, 2021

Signifier Medical Technologies

% Mr. Jay Mansour
Director, Medical devices
Biotech Research Group
3810 Gunn Highway
Tampa, Florida 33618

Re: DEN200018

Trade/Device Name: eXciteOSA without remote control, eXciteOSA with remote control

Regulation Number: 21 CFR 872.5575

Regulation Name: Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea

Regulatory Class: Class II

Product Code: QNO

Dated: March 9, 2020

Received: March 24, 2020

Dear Mr. Mansour:

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 eXciteOSA without remote control, eXciteOSA with remote control, a prescription device under 21 CFR Part 801.109 with the following indications for use:

eXciteOSA is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce snoring and mild obstructive sleep apnea (AHI<15) for patients that are 18 years or older.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the eXciteOSA without remote control, eXciteOSA with remote control, and substantially equivalent devices of this generic type, into Class II under the generic name neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea.

FDA identifies this generic type of device as:

Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea. A neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea consists of a removable intraoral mouthpiece that uses electrodes to deliver neuromuscular stimulation to the tongue to strengthen tongue musculature to reduce snoring and obstructive sleep apnea.

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 March 24, 2020, FDA received your De Novo requesting classification of the eXciteOSA without remote control, eXciteOSA with remote control. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the eXciteOSA without remote control, eXciteOSA with remote control 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 eXciteOSA without remote control, eXciteOSA with remote control 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 Measures
Adverse tissue reaction	Biocompatibility evaluation
Interference with other devices/electrical shock	Electrical safety testing Electromagnetic compatibility (EMC) testing Battery safety testing Wireless coexistence testing Labeling
Use error leading to pain, discomfort, or injury	Human factors assessment Software verification, validation, and hazard analysis Electrical safety testing Labeling
Mucosal or skin overheating or burn	Software validation, verification, hazard analysis Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Infection	Labeling

In combination with the general controls of the FD&C Act, the neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea is subject to the following special controls:

- (1) Performance testing must demonstrate the wireless compatibility, electrical safety, battery safety, and electromagnetic compatibility of the device in its intended use environment.

- (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) Patient labeling must include:
 - (i) Information on device components, setup, and use of the device including placement of sensors and mouthpieces, and images or illustrations;
 - (ii) A summary of technical specifications;
 - (iii) Instructions on how to clean and maintain the device;
 - (iv) A statement that the patient should maintain regular follow up visits with dentist and sleep specialist; and
 - (v) A statement that patients should have a comprehensive dental examination prior to using this device.
- (5) A human factors assessment must evaluate simulated use of the device to demonstrate that the user can correctly use device based on the labeling and instructions for use.

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 neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea 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 Anita Belani at 301-796-3944.

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