May 16, 2024

Signifier Medical Technologies Ltd
% Darren Scheer
Principal
RegChoice LLC
13014 N. Dale Mabry Hwy STE 803
Ste 803
Tampa, Florida 33618

Re: K240328
Trade/Device Name: eXciteOSA without remote control (3000); eXciteOSA with remote control (6000)
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: February 2, 2024
Received: February 5, 2024

Dear Darren Scheer:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240328

Device Name

eXciteOSA without remote control (3000);
eXciteOSA with remote control (6000)

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K240328

510(k) Summary

Prepared on: 2024-04-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Signifier Medical Technologies Ltd
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Correspondent Contact Telephone	813-363-3004
Correspondent Contact	Dr. Darren Scheer
Correspondent Contact Email	dscheer@regchoice.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	eXciteOSA without remote control (3000); eXciteOSA with remote control (6000)
Common Name	Neuromuscular tongue muscle stimulator for the reduction of snoring and obstructive sleep apnea
Classification Name	Neuromuscular Tongue Muscle Stimulator For The Reduction Of Snoring And Obstructive Sleep Apnea
Regulation Number	872.5575
Product Code	QNO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223446	eXciteOSA without remote control, eXciteOSA with remote contr	QNO

Device Description Summary

21 CFR 807.92(a)(4)

eXciteOSA® is a removable tongue muscle stimulation device that delivers neuromuscular stimulation to the tongue in order to reduce mild obstructive sleep apnea (AHI <15) and snoring for patients that are 18 years or older. The small electric currents delivered through the mouthpiece stimulate the tongue and improve its muscle function. The improved function of the tongue muscle will help in keeping the upper airway open during sleep and reduce the vibration of the throat region.

Two tabs of the mouthpiece sit comfortably above and below the tongue. The mouthpiece is designed such that when the mouth is gently closed, it will naturally sit around the tongue and won't move during the therapy session. The device can be used at any point during the day.

The device can be controlled by a smartphone application. This app can be downloaded from the App store (Apple iOS) or Play Store

(Google Android). The mobile app software can be used on iPhone 11, iPhone 11 Pro & iPhone 11 Pro Max and above, with iOS 15.0 and higher. The mobile app software can also be used with Android devices with Bluetooth support and Android 10.0 and above. eXciteOSA® uses Bluetooth Smart; mobile devices used must be compatible with Bluetooth Smart.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Other than the replacement of the microcontroller from a different manufacturer (difference #1), and for the minor changes listed below (difference #2), this subject device has the same technological characteristics of the predicate device.
The first difference, replacement of the microcontroller, was required due to supply issues and is not critical to the intended therapeutic use of the device. This change did not impact the functionality or safety of the device, as evidenced in the testing results and risk analysis submitted with this notification.
The second difference includes the following minor changes:

- Layout of components within control unit to accommodate new MCU
- Replacement of battery fuel gauge
- Mouthpiece trigger comparator circuit to detect mouthpiece presence with lower applied voltage
- Moisture detection to warn user of moisture presence in the USB-C connector, with feedback via an ADC signal to the MCU
- Changed from blue and amber LEDs to blue, yellow, and red, which are much more visible. The yellow LED position was also slightly moved so it is no longer under the blue 'S' logo, for better visibility.
- External DAC to match the output resolution of the previous MCU internal DAC
- Optional extender cable to be provided to end-user

These minor changes (difference #2) do not rise to the need of submitting a 510(k) in accordance with FDA Guidances, Deciding When to Submit a 510(k) for a Change to an Existing Device (2017) and The Special 510(k) Program(2019). These changes are justified via risk analysis.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Clinical tests were not performed. Various non-clinical tests were performed. Relevant safety and performance studies were conducted according to IEC standards 60601-1-2, 60601-1, 60601-1-11, 60601-1-6, and 60601-2-10. Additional device-specific electrical, software, firmware, and functional verification testing was performed. The device passed all relevant tests. These test results support the finding of substantial equivalence to the predicate device.