January 18, 2023

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

Re: K223446
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: November 14, 2022
Received: December 19, 2022

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223446

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.

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510(k) Summary

Prepared on: 2022-11-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Signifier Medical Technologies Ltd
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Applicant Contact	Mr. Yasser Zayni
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Correspondent Name	RegChoice LLC
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Correspondent Contact Telephone	8133633004
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
DEN200018	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 5S, iPhone 6/6 Plus, iPhone 6s/6s Plus, iPhone 7/ 7 Plus, iPhone 8/8 Plus, iPhone X, with iOS 11.0 and higher. The mobile app software can also be used with Android devices with BLE support (Bluetooth 4.0) and Android 7.0 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 for the deletion of some contraindications (difference #1) and for minor software/firmware updates (difference #2), this subject device has the same technological characteristics of the predicate device.
The first difference, in contraindications, is not critical to the intended therapeutic use of the device, as evidenced in the three supporting sources of data and the associated risk analysis.
The second difference, in software/firmware minor updates, does not rise to the need of submitting a 510(k) in accordance with FDA Guidance Deciding When to Submit a 510(k) for a Software Change to an Existing Device. These changes are justified via risk analysis.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical and/or clinical tests were not performed, as the subject device and the predicate device are the same and no physical changes were made.