January 27, 2022

Zelegent, Inc.
David Humbert
Vice President, Clinical and Regulatory Affairs
4250 Executive Square, Suite 675
La Jolla, California 92037

Re: K213475
Trade/Device Name: Elevo Snoring Intervention Set
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: October 28, 2021
Received: October 29, 2021

Dear David Humbert:

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, 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.

510(k) Number *(if known)*
K213475

Device Name

Elevo Snoring Intervention Set

Indications for Use *(Describe)*

The Elevo Snoring Intervention Set is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.

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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Section 5 – 510(k) Summary - K213475

This summary of 510(k) safety and effectiveness information is being submitted pursuant to the requirements of 21 CFR 807.92.

SUBMITTER:	Zelegent, Inc. 4250 Executive Square, Suite 675 La Jolla, CA 92037
CONTACT PERSON:	David C. Humbert, RAC Vice President, Regulatory and Clinical Affairs
DATE PREPARED:	October 28, 2021
TRADE NAMES:	Elevo® Snoring Intervention Set
TRADE NAMES (OTHER):	Elevo® Kit Elevo® Kit Snoring Intervention Device Elevo® Set Elevo® Set Snoring Intervention Device
COMMON NAME:	Anti-Snoring Device
CLASSIFICATION:	Class II
PRODUCT CODE:	LRK - Device, Anti-Snoring 872.5570, intraoral devices for snoring
PREDICATE DEVICE:	Elevo® Kit Snoring Intervention Device (K181107)
DEVICE DESCRIPTION:	The Elevo® Snoring Intervention Set is comprised of three (3) sterile, absorbable, barbed, poly(L-lactide-co-D L-lactide) sutures and three (3) corresponding disposable, sterile, single use suturing needles. A silk disposable tension suture (DTS) is attached to the proximal end of each of the poly(L-lactide-co-D L-lactide) barbed suture implants. The proximal end of the DTS is secured to the suturing needle handle during device assembly. One (1) Pilot Hole Initiation Tool (PHIT) completes the contents of the set.
INDICATIONS FOR USE:	The Elevo® Snoring Intervention Set is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.

INTENDED USE:

The Elevo® Snoring Intervention Set is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring due to palatal flutter in some individuals.

EQUIVALENCE TESTING:

The material characteristics of the poly(L-lactide-co-D L-lactide) suture implant have been evaluated for equivalence to the material characteristics of the polydioxanone (PDO) suture implant of the predicate device (Elevo® Kit Snoring Intervention Device K181107), including tensile strength and absorption profile. The comparative results demonstrate that the subject device material characteristics are equivalent to the material characteristics of the predicate device.

CONCLUSION:

The Elevo® Snoring Intervention Set with sterile, absorbable, barbed, poly(L-lactide-co-D L-lactide) sutures is substantially equivalent to the Elevo® Kit Snoring Intervention Device (K181107) with sterile polydioxanone (PDO) sutures. The device is indicated for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.

In vitro bench test data demonstrate that the Elevo® Snoring Intervention Set with poly(L-lactide-co-D L-lactide) sutures performs as anticipated, and the device raises no new questions of safety and effectiveness when compared to the predicate device.