December 6, 2018

Zelegent, Inc.
David Humbert
Vice President, Regulatory and Clinical Affairs
5151 California Avenue
Irvine, CA 92617

Re: K181107
Trade/Device Name: Elevo® Kit Snoring Intervention Device
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: November 5, 2018
Received: November 6, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181107

Device Name

Elevo® Kit Snoring Intervention Device

Indications for Use *(Describe)*

The Elevo® Kit Snoring Intervention Device 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

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

Section 807.92(a)(1):

SUBMITTER:	Zelegent, Inc. 4250 Executive Square, Suite 200 La Jolla, CA 92037
CONTACT PERSON:	David C. Humbert, RAC Vice President, Regulatory and Clinical Affairs 650.763.8282 x102
DATE PREPARED:	December 3, 2018

Section 807.92(a)(2):

NAME OF DEVICE:	Elevo® Kit Snoring Intervention Device
TRADE NAME:	Elevo® Kit Snoring Intervention Device
PROPRIETARY NAME:	Elevo® Kit Snoring Intervention Device
COMMON NAME:	Snoring Mitigation Device
CLASSIFICATION NAME	Device, Anti-Snoring
PRODUCT CODE:	LRK - Device, Anti-Snoring 872.5570, intraoral devices for snoring

Section 807.92(a)(3):

PREDICATE DEVICE:	Pillar™ Palatal Implant System Manufactured by Medtronic XOMED, Inc.
PREDICATE DEVICE 510(k):	K110623
REFERENCE DEVICE:	Quill™ Absorbable Suture Manufactured by Surgical Specialties Corporation dba Angiotech
REFERENCE DEVICE 510(k):	K132268

Section 807.92(a)(4):

DEVICE DESCRIPTION:

The Elevo® Kit Snoring Intervention Device is comprised of three (3) sterile, absorbable, and barbed, polydioxanone (PDO) sutures and three (3) corresponding disposable, sterile, single use suturing needles. A disposable tension suture (DTS) is attached to the proximal end of each of the barbed PDO suture implants. The proximal end of the DTS is secured to the suturing needle handle during device assembly.

HOW THE DEVICE FUNCTIONS:

The Elevoplasty® procedure is a minimally-invasive physician's office intervention to treat mild to moderate snoring. It works by stiffening and shortening the soft palate. Elevoplasty® is accomplished by way of a custom designed resorbable suture implant that exerts it effect on the soft palate similarly to the way standard barbed sutures are used in plastic surgery during minimally-invasive facelift procedures. Its barb configuration and length are optimized for providing tissue apposition specifically in the soft palate. The bi-directional barbs allow for implantation of the suture without the need for surgical knots or swaged needles, and without the need for anchoring to any bone structure.

SCIENTIFIC CONCEPT & PERFORMANCE CHARACTERISTICS:

The barbed suture implant is deployed into the soft palate by way of a specialized curved suturing needle that is comprised of medical grade stainless steel. Three (3) Elevo® curved suturing needles, each pre-loaded with a resorbable barbed suture implant, are packaged into each Elevo® Kit, with the intention that one kit will be used during each patient's Elevoplasty® procedure.

To perform Elevoplasty® the physician first confirms that each Elevo® suture implant is provided pre-loaded into its specialized suturing needle delivery device. Applying gentle pressure on the handle, the physician advances the tip of the suture delivery needle in a gentle arch motion through the uvular and the levator palatine muscles toward the posterior end of the soft palate (i.e., the uvula). The marker band located on the suture delivery needle shaft (the depth insertion marker) may be used as a visual reference. If the physician employs the depth insertion marker as a visual reference, the guideline is to advance the needle far enough that the depth insertion is completely beneath the tissue (i.e., no longer visible). As a general guideline the physician advances the tip distally until it has traveled approximately 25-30 mm through the soft palate to an area approximately 8-10 mm from the distal ridge of the soft palate. The physician then releases the proximal end of the disposable tensioning suture from the handle.

Once the physician is satisfied with the depth, he/she reverses the direction of motion of the handle, thereby retracting the needle out of the soft palate in a backward re-tracing of the simple arc motion that was just completed. This process results in the resorbable barbed suture implant being left in place in the soft palate, with both sets of barbs engaged in soft tissue and the disposable tension suture (DTS) protruding out of the patient's palate and mouth.

The physician then repeats this piercing, advancing, and pulling-out sequence with the two (2) remaining Elevo® suture implants included in the kit (or just one [1] more implant if the patient has an unusually narrow palate anatomy and the physician determines that a total of just two [2] implants are needed). A minimum of two (2) and a maximum of three (3) Elevo® suture implants are deployed at the physician's discretion, in each case within the width of the patient's soft palate. If three (3) Elevo® suture implants are placed: one implant is inserted along the patient's midline and is advanced distally. The remaining two (2) implants are generally inserted approximately 5-10 mm laterally on each side and advanced in a slight radiating pattern so that the tip of the suture implant resides approximately 10-15 mm lateral to the distal end of the fully-advanced middle suture implant. Physicians have some discretion over exactly what angle in which to direct the implants, with the guideline simply being using a simple in-and-out motion to achieve some degree of vertical soft palate tension or lift.

Once all implants are placed, the ends of the black silk DTS protrude from the patient's palate and open mouth. For each patient, the physician judges whether some degree of soft palate lift has already been achieved by the upward motion exerted on the implant while the needle is removed, or if some additional upward force on the DTS is indicated. If indicated, the physician gently pulls on each DTS with the goal of causing a mild tissue apposition (i.e., "accordion-ing") of the soft palate tissue. This action is meant to slightly raise, shorten, and stiffen the soft palate with the proximal barb row engaging with the tissue and acting like a gentle ratchet to maintain the tension on the suture. This is the key scientific concept by which the device exerts its therapeutic benefit. This tension is achieved entirely within the soft tissue – there is no need nor occasion for any interaction with hard tissue or palatal bone.

After being satisfied that approximately 1-4 mm of soft palate lift has been achieved, the physician then cuts the extending DTS sutures with scissors. This action tends to cause the suture implants to retract slightly into

the tissue, ensuring that the suture does not protrude and result in tongue-mediated awareness for the patient. If the proximal ends of any of the suture implants protrude slightly after the DTS has been cut, which sometimes occurs due to the natural recoil of the soft palate, the physician uses a standard forceps or hemostat tool to tuck the tip back under the soft palate tissue. The mild retraction into the tissue may also serve as a barrier to infection risk as the implant becomes imbedded.

DESIGN, MATERIALS USED & PHYSICAL PROPERTIES:

The Elevo® suture implant is comprised of polydioxanone. Polydioxanone has been found to be non-antigenic and to elicit only a slight tissue reaction during absorption. The bi-directional barbs allow for implant of the suture without the need for surgical knots or swaged needles. Each Elevo® suture implant is provided pre-loaded into a specialized suturing needle delivery device. Three (3) such pre-loaded suture implants on delivery devices are packaged into each Elevo® Kit, with the intention that one kit will be used during each patient's Elevoplasty® procedure.

The Elevo® suturing needle is comprised of medical grade stainless steel. The curved ergonomic handle is comprised of ABS plastic over-molded onto the needle for strength.

Section 807.92(a)(5):

INTENDED USE:

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

Patients with consistent nighttime snoring without sleep apnea, who wish to avoid uvulopalatalpharyngoplasty ("UPPP") surgery, and are not interested in wearing an anti-snoring dental appliance are eligible for an outpatient in-office Elevoplasty® procedure.

Snoring is an easily-observable symptom that can be caused by a variety of anatomical pathologies. Obstruction of the airway by tissue, either the soft palate or the posterior end of the tongue, results in the build-up of a partial vacuum as the patient's pulmonary diaphragm contracts in an effort to inhale. The negative pressure created by the diaphragm grows until it is enough to make the tissue obstructing the airway "slip" and allow some air to pass. The inflowing air causes a slight reduction of negative pressure, which allows the tissue to fall back into obstruction, and the negative

pressure builds again. This cycle can repeat twenty (20) or more times per breath during sleep, resulting in the familiar "rat-tat-tat" sound of snoring. Reducing the length of the soft palate, even slightly, may change this dynamic by limiting the amount of tissue causing the transient airway obstruction. Even a small increase in the diameter of the airway may significantly increase free air flow as the cross-sectional area is approximately three times the square of the radius.

Approximately twenty percent (20%) of the adult population of the developed world consistently snores at night at volumes high enough to disturb sleeping partners. This results in strained relationships and the possible breakdown of the family unit, as well as real physiologic harm to the snorer. Of audible snorers, approximately one in six (1/6) suffer from obstructive sleep apnea (OSA), a condition in which tissues of the nasopharynx fall into positions that block the airway, restricting breathing during sleep to an extent that causes the patient repeated cycles of breathing cessation (apnea) and subsequent gasping for air without regaining consciousness. The OSA patient is deprived of restful sleep and suffers from poor tissue oxygenation, impaired memory, cognition, and daytime mental functioning, and in extreme cases runs the risk of sudden death from oxygen deprivation (asphyxiation) during sleep.

INTENDED USE & INDICATIONS FOR USE SUMMARY:

The **Intended Use** of the Elevo® Kit Snoring Intervention Device is identical to the predicate device identified in K110623:

Indications for use of the Elevo® Kit Snoring Intervention Device include symptomatic, habitual, and social snoring due to palatal flutter.

The **Indications for Use** of the Elevo® Kit Snoring Intervention Device is identical to the predicate device identified in K110623:

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

Section 807.92(a)(6):

EQUIVALENCE TESTING:

The material characteristics of the Elevo® suture implant have been evaluated for equivalence to the reference device (Quill™ Absorbable Suture K132268). The comparative results indicate equivalence to the reference device.

A direct comparison of key characteristics between the Elevo® Kit Snoring Intervention Device and the predicate device (Pillar™ Palatal Implant System K110623) has demonstrated equivalence with respect to clinical utility of the subject device. The following **Tables** (excerpted and revised[1] from *Section 12, Substantial Equivalence Discussion* of this Premarket Notification) provide a comprehensive summary of equivalence between the two devices:

Characteristic	Elevo® Kit Snoring Intervention Device	Predicate Device: Pillar™ Palatal Implant System	Reference Device: Quill™ Synthetic Absorbable Barbed Suture
510(k) Number	K181107	K110623	K071989 K113744 K123877 K132268
Indications for Use	The Elevo® Kit Snoring Intervention Device is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.	The Pillar™ System is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals.	Quill™ Synthetic Absorbable Barbed Sutures are indicated to close easily approximated edges of dermis where use of absorbable sutures is appropriate.
Common/Usual Name	Device, Anti-Snoring	Device, Anti-Snoring	Polydioxanone Absorbable Surgical Suture
Regulation No.	21 CFR § 872.5570	21 CFR § 872.5570	21 CFR § 878.4840
Classification Name	LRK – Device Anti-Snoring	LRK – Device Anti-Snoring	Absorbable polydioxanone surgical suture
Class	II	II	II
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Material	Absorbable Polydioxanone (PDO)	Braided polyester filaments	Absorbable Polydioxanone (PDO)

Table 5-1: Device Comparative Regulatory Information

[1] Revisions include the addition of *K181107* to the 510(k) Number row and change to the trademarked status of the device name “Elevo™” to the registered device name “Elevo®”

Characteristic	Elevo® Kit Snoring Intervention Device	Predicate Device: Pillar™ Palatal Implant System	Reference Device: Quill™ Synthetic Absorbable Barbed Suture
Labeling: Sterile, Single Use	Yes	Yes	Yes
Implant Materials	Absorbable Polydioxanone (PDO)	Woven polyester fiber filament	Absorbable Polydioxanone (PDO)
Implant Component Description	Absorbable Surgical Suture	Non-absorbable, permanent, polyester filament	Absorbable Surgical Suture
Outpatient – Office Based Procedure	Yes	Yes	Device is indicated for soft tissue approximation where use of an absorbable suture is appropriate.
Mechanism of Action Delivery Method	Disposable, sterile, single use, handheld suturing needle and proprietary suture implant technique	Disposable, sterile, single use, handheld pellet delivery needle	Handheld suturing needle
Implant Manufacturing Method	Injection molded	Multiple polyester fibers woven & and fused with two ultrasonic welds	Injection molded and/or machine extruded
Biocompatible	Yes	Yes	Yes
Device Description – General	The kit is intended as a treatment option for snoring and consists of an implant and a delivery tool. The device is designed to stiffen the tissue of the soft palate and to reduce the dynamic flutter of those tissues without interfering with the normal function of the soft palate.	The system is intended as a treatment option for snoring and consists of an implant and a delivery tool. The device is designed to stiffen the tissue of the soft palate and to reduce the dynamic flutter of those tissues without interfering with the normal function of the soft palate.	The device is a synthetic absorbable suture available in various suture length and needle configurations in USP Sizes 3-0 and 4-0. Each suture has bi-directional barbs along the axis of the suture strand. Barbs allow for tissue approximation without the need for surgical knots.

Table 5-2-a: Device Technological Characteristics

Characteristic	Elevo® Kit Snoring Intervention Device	Predicate Device: Pillar™ Palatal Implant System	Reference Device: Quill™ Synthetic Absorbable Barbed Suture
Device Description – Implant	The implant is a barbed, absorbable suture that is injection molded of polydioxanone (PDO). The barbs are designed to allow for a knotless application during implant of the device. The distal stirrup shape and the proximal circular shape facilitate loading of the device onto the suturing needle during final packaging. The delivery tool is designed with a crochet-hook at the distal end and is manufactured from stainless steel that has been fabricated with a 60 degree curve to facilitate implant of the barbed suture.	The implant is a cylindrical shaped segment of braided polyester filaments. The delivery tool is comprised of a handle and needle assembly that allows for positioning and placement of the implant submucosally in the soft palate. The implant is permanent while the delivery tool is disposable.	The implanted suture is a barbed, absorbable suture that is extruded from polydioxanone (PDO). The bi-directional barbs are designed to allow for a knotless application during implant of the suture.
Performance Testing	Dimensional integrity, mechanical performance and reliability, biocompatibility, insertion ability and pre-clinical performance. Elevo™ is a suture and was tested for tensile strength (as applicable) and needle attachment. Elevo™ was also tested for *in vitro* post hydrolysis tensile strength.	Dimensional integrity, mechanical performance and reliability, biocompatibility, insertion ability and pre-clinical performance.	USP Monograph for absorbable sutures for tensile strength (as applicable) and needle attachment. *In vitro* post hydrolysis testing.

Table 5-2-b: Device Technological Characteristics

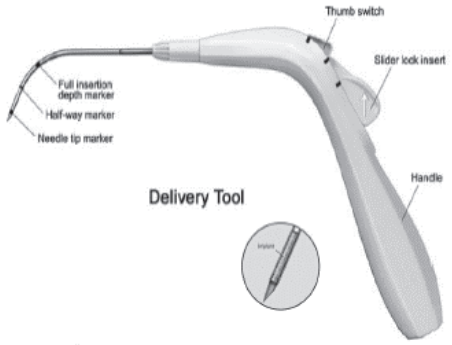
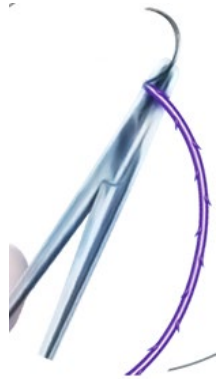
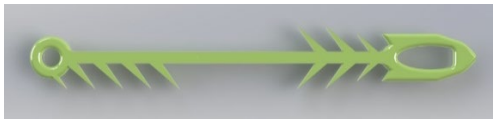
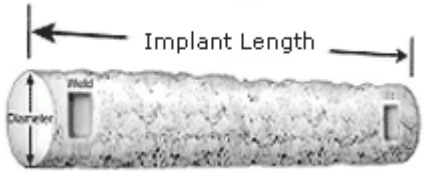
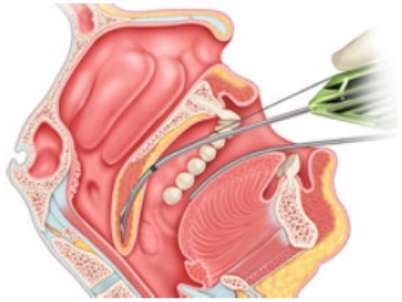
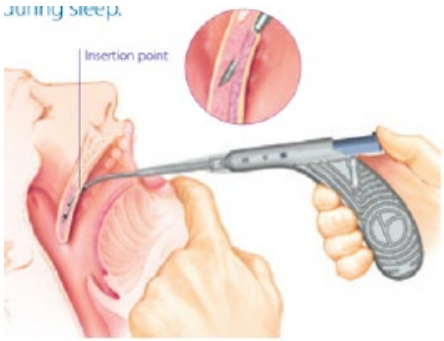
Characteristic	Elevo® Kit Snoring Intervention Device	Predicate Device: Pillar™ Palatal Implant System	Reference Device: Quill™ Synthetic Absorbable Barbed Suture
Delivery Tool			
Implant Length	 1.905 cm	 1.8 cm	 Length Not Applicable
In Vivo Delivery			Not Applicable

Table 5-3: Device Physical Characteristics

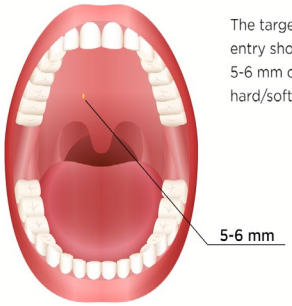
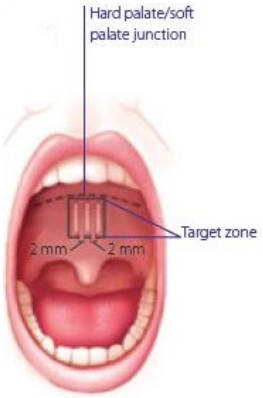
Procedure	Elevo® Kit Snoring Intervention Device	Predicate Device: Pillar™ Palatal Implant System
Preparation	Antibiotic not required	An appropriate broad-spectrum antibiotic should be given
	Prepare site with a short-acting oral antiseptic	Prepare site with an oral antiseptic
	Inject site with no more than 0.75 cc total lidocaine in up to 3 locations around the soft palate in order to avoid hydro-dissection.	Inject site with a local anesthetic (2 – 3 cc) nine injections 1 cm apart, starting 1 mm anterior to the hard palate junction.
Insertion	Place needle slightly to the side of the soft palate midline raphe.	Place needle high in the palate. Insertion points should be as close to the junction of the hard and soft palate as possible – 1 mm anterior to the junction is ideal.
Target Zone		
Deployment	Advance the tip of the suture delivery device in a gentle arch motion through the uvula and the levetor palatine muscles. Reverse direction and retract the needle. The barbed suture is deployed. Pull on each disposable tension suture to effect mild tissue apposition and lift the soft palate tissue.	Advance slider from start position. Stop advancing slider when it reaches halfway deployment position. Withdraw the needle.
Inspection	Cut the disposable tension sutures with scissors, and inspect the implant region.	Inspect the needle insertion site. If a portion of the implant is exposed, it must be gently removed with forceps to mitigate risk of infection or extrusion.

Table 5-4: Clinical Technique Comparison

Section 807.92(b)(1):

NONCLINICAL TESTING: A brief discussion/summary of nonclinical testing (excerpted with minor revisions) from *Section 18, Performance Testing, Bench* from this Premarket Notification for the Elevo® Kit Snoring Intervention Device is provided following:

The Elevo® Kit Snoring Intervention Device is a manually-operated, single-use, tapered needle suture delivery system. There are no mechanical or moving parts in the kit. The tapered needle point is designed to pierce the mucosal tissue of the soft palate without cutting it. The crochet-type tip of the tapered needle facilitates attachment of the Elevo™ implant to the needle. The Disposable Tension Suture (DTS) is attached to the proximal end of the Elevo™ implant. The proximal end of the DTS is attached to the handle *cleat* during the Kit assembly process.

Performance (bench) testing of the Elevo® Kit Snoring Intervention Device was conducted pursuant to the following standard test methods:

- STM001, Standard Test Method, Elevo® Implant Tensile Strength (see **Appendix 18-1**)
- TM002, Standard Test Method, Elevo® DTS Tensile Strength (see **Appendix 18-2**)
- STM003, Standard Test Method, Suturing Needle Proof Load (see **Appendix 18-3**)
- STM004, Standard Test Method, Suturing Needle Tip Bending (see **Appendix 18-4**)

Performance (bench) testing of the packaging system designed for the Elevo® Kit Snoring Intervention Device, the corresponding 6-month shelf life verification, and the Design Verification testing described in the above identified Standard Test Methods are encompassed in the following test protocol:

- TP002-001, Test Protocol, Packaging Validation and 6-month Shelf Life Verification of the Elevo® Kit Snoring Intervention Device (see **Appendix 18-5**)

The results of the performance (bench) testing of the Elevo® Kit Snoring Intervention Device are provided in the following test report:

- TR002-001, Test Report, Packaging Validation and 6-month Shelf Life Verification of the Elevo® Kit Snoring Intervention Device (see **Appendix 18-6**)

A comprehensive description of the objectives, test methods, test articles, study endpoints, pass/fail criteria, and the shelf life for the Elevo® Kit Snoring Intervention Device packaging system is provided in **Section 14** of this submission.

Section 807.92(b)(2):

CLINICAL TESTING:

The Elevo® Kit Snoring Intervention Device was clinically evaluated in human subjects during the S.I.LE.N.C.E. Study (**S**noring **I**ntervention via E**le**voplasty in a **N**on-surgical **C**linical **E**nvironment). The study was designated a Non-Significant Risk clinical trial by FDA and was conducted between March and September 2017.

STUDY TYPE/DESIGN:

Single group compared to Baseline, non-randomized, multi-center, prospective, safety and efficacy study.

PATIENT POPULATION STUDIED

Adult patients ≥ 22 years (no maximum age) with simple snoring; an apnea-hypopnea index (AHI) score of <15; no prior surgical treatment for snoring; and with a bed/sleep partner willing and capable of providing Informed Consent.

PATIENT SUB-POPULATION ANALYSIS:

	Subset Analysis: 31 patients who began the study with Baseline AHI of 5 or below
Day 30 reduction in Snoring VAS	24.5%
Number of patients' bed partners' reporting Day 30 results	31
Day 90 reduction in Snoring VAS	33.6%
Number of patients' bed partners' reporting Day 90 results	27
Day 180 reduction in Snoring VAS	27.3%
Number of patients' bed partners' reporting Day 180 results	27

STUDY SUBJECT DEMOGRAPHICS & DESCRIPTION:

Fifty-two (52) Study Subjects were enrolled in the trial, of which eighteen (18) were female and thirty-four (34) were male. The Study Subject's ranged in age from twenty-two (22) years to seventy-eight (78) years, with a mean of forty-four (44) years of age.

Each Study Subject presented with a self-identified snoring problem and tested negative for Obstructive Sleep Apnea pursuant to the literature definition: Apnea Hypopnea Index (AHI) <15.

The Study Subject and the Co-Participant/Bed Partner were consented and were trained on the use of an external outcomes-tracking database. The database was constructed specifically for the S.I.LE.N.C.E. Study by trials.ai, a company that specializes in electronic patient-reported outcomes (ePRO) and electronic observer reported outcomes (eORO). The Bed Partner's objective scoring of each Study Subject's snoring severity at specific time points were entered into the database. The Clinical Coordinators at each investigational site did not obtain snoring results in order to minimize the opportunity for bias.

STUDY SUBJECT METRICS:

The Visual Analog Scale (VAS) 0 – 10 score assessment of the Study Subject's snoring severity was entered at four (4) time points during the trial: (1) Prior to the Elevoplasty® procedure (Baseline), (2) thirty (30) days after the procedure, (3) ninety (90) days after the procedure, and (4) one hundred eighty (180) days after the procedure. Hence, with fifty-two (52) Study Subjects treated during the trial, the Bed Partners were required to enter a collective total of two hundred eight (208) VAS scores (52 x 4 = 208). Although not all scores were entered exactly on time due to Study Subject follow-up challenges, most scores were entered within 2-5 days of their scheduled date.

A variety of Secondary Endpoints were also collected during the trial. These included two surveys (Epworth Sleepiness Scale and Pittsburgh Sleep Quality Index) that the Study Subjects themselves were prompted to complete at the same four (4) endpoints discussed above. In addition to the surveys, each Study Subject was required to complete the same home sleep study using the SNAP® Diagnostics Model 8 Ventilatory Effort Recorder device. Results of the SNAP® home sleep study recordings were analyzed by SNAP® Diagnostics, Inc., with a minimum of four (4) hours of recording required for each Study Subject file to be analyzed. Audio files measured for the frequency of four (4) pre-defined types of snoring noise events detected by the SNAP® Diagnostics staff algorithms.

SAFETY & EFFECTIVENESS DATA:

The **clinical safety** of the Elevo® Kit Snoring Intervention Device meets or exceeds the clinical safety of the predicate device (Pillar™ Palatal Implant System), as evidenced by the comparable safety data presented in the Tables provided in *Section 12, Substantial Equivalence Discussion* of this 510(k). The safety of the Subject Device has been demonstrated in a well-controlled Non-significant Risk (NSR) clinical study, in which zero ("0") adverse events were reported and only two (2) Elevo® suture implants were reported to have been felt by patients. In both cases of palpable Elevo® implants, the extruding section of the implant was treated with a simple trimming of the protruding portion of the implant in a brief follow-up office visit, thereby resolving the issue. This simple trimming with scissors involves no anesthesia, no bleeding, and no pain. By contrast, cases of extruding implants of the Pillar™ Palatal Implant System predicate device cannot be resolved in this simple manner. Instead of a simple trimming of the protruding portion, Pillar implants are too hard to be cut with scissors, so any palpable extrusion necessitates complete explantation of the implant. Explantation of a Pillar implant involves re-anesthetizing the patient, and pulling the implant out (or sometimes cutting it out with a #11 scalpel blade) causing tissue trauma – the site typically bleeds.

ANTICIPATED ADVERSE EVENTS:

Four (4) anticipated adverse events were reported during the study. Each event was prospectively defined in the S.I.LE.N.C.E. Study Protocol and are described below:

1. Trouble swallowing; sore throat – sharpness feeling on the throat right side.

2. Patient reported that a "stitch" was sticking straight down, was very sharp and was affecting the patient's speech. The patient was brought into the investigational center the same day as the report, examined by the investigating clinician who observed the proximal end of the midline barbed implant protruding from the site of administration. The end of the implant was trimmed by the clinician, at which point the patient reported immediate relief.

3. Patient reported and described dysphagia on post-operative night #1 that was resolved upon waking on Post-operative Day #1.

4. Patient reported superficial bruising in the roof of the mouth. Patient was seen in the office by the investigating clinician, who examined the site and concluded that the event is an expected risk related to participation in the trial.

Each of the four (4) events meet the definition of *Common Treatment Events* as prospectively defined in the S.I.LE.N.C.E. Study Protocol (i.e., dysphagia, sore throat, palpable suture, oral hematoma). Based upon this rationale, the Sponsor maintains that there were zero Unanticipated Adverse Events in the S.I.LE.N.C.E. Study.

CLINICAL SAFETY CONCLUSION:

The Sponsor concludes that the clinical safety of the Elevo® Kit Snoring Intervention Device is equivalent to, or exceeds, the clinical safety of the predicate device.

The **clinical efficacy** of the Elevo® Kit Snoring Intervention Device is comparable to the predicate device, as evidenced by the clinical data presented in the Tables provided in *Section 12, Substantial Equivalence Discussion* of this 510(k). Snoring severity - as measured by the most meaningful and relevant metric: each patient's bed partner's 0-10 snoring severity rating - was reduced by an average 25% or more at the three follow-up time points measured: Day 30, Day 90, and Day 180 post-procedure. Notably, the duration of snoring severity reduction appears to exceed the resorption time of Elevo® implants. This observation is consistent with the Sponsor's and clinical advisors' theory that the physical tissue apposition of the soft palate caused by the pulling of the implant induces a secondary tissue remodeling and contraction process that persists after the implant has been replaced by scar tissue.

Of the four clinical efficacy results of the Pillar™ Palatal Implant System predicate, the fourth one (the clinical study of 40 patients with chronic primary snoring) appears to be the most relevant benchmark to which to compare the Elevo® Kit Snoring Intervention Device efficacy results. This is because the first study (the one that used a 0-100 VAS score) had only 12 patients. The second study had 106 patients but its efficacy was stated only qualitatively, with no percentage reduction nor p-values. The third study (the one with the biggest drop in bed partner VAS) had only 15 patients.

When comparing the 52-patient Elevo® Kit Snoring Intervention Device efficacy results from the S.I.LE.N.C.E. Study to the 40-patient fourth Pillar study (see **Table 5-5**), we observe:

Characteristic	Elevo® Kit Snoring Intervention Device S.I.LE.N.C.E. Study Results	Subset of S.I.LE.N.C.E. Study Results pertaining only to those patients with a pre-procedure AHI score of 5 or below	Predicate Device: Pillar™ Palatal Implant System 4th Study
Number of patients	N = 52	N=31	N = 40
Number of Patients Completing All Endpoints	N = 45 (87%)	N=27 (87%)	N = 32 (80%)
Percentage of patients lost to follow-up	13%	13%	20%
Bed Partner Mean Snoring Severity 0-10 VAS rating at Baseline	7.81 ± 1.59	7.65 ± 1.58	7.1 ± 2.0
Bed Partner Mean Snoring Severity 0-10 VAS rating at Day-30	5.79 ± 2.33 $p < 0.001$	5.77 ± 2.45 $p < 0.001$	Not measured
Bed Partner Mean Snoring Severity 0-10 VAS rating at Day-90	5.42 ± 2.33 $p < 0.001$	5.04 ± 2.21 $p < 0.001$	Day-90 4.2 ± 2.7 $p < 0.05$
Bed Partner Mean Snoring Severity 0-10 VAS rating at Day-180	5.40 ± 2.28 $p < 0.001$	5.52 ± 2.42 $p < 0.001$	Not measured

Table 5-5: Comparative Clinical Data

Compared to the most extensive known clinical study of the four (4) available for the predicate device, the efficacy results of the Subject Device - measured by the same primary endpoint outcome measurement (bed partner snoring severity 0-10 VAS) – demonstrate a greater degree of statistical significance, and had more patients complete the study with a lower lost-to-follow-up rate. While it did not alleviate snoring in 100% of the patients, the mean outcome of the Elevoplasty® procedure was so positive that there is less than 1/10th of 1% chance that the alleviation of snoring observed at Day 30, Day 90, and Day 180 post-procedure was due to chance.

CLINCIAL EFFICACY CONCLUSION: The Sponsor concludes that the clinical efficacy of the Elevo® Kit Snoring Intervention Device is equivalent to the clinical efficacy of the predicate device.

Section 807.92(b)(3):

CONCLUSIONS: The Elevo® Kit Snoring Intervention Device has the same Indications for Use and Intended Use as the predicate device, Pillar™ Palatal Implant System.

The implantable component of the Subject Device is manufactured using polydioxanone (PDO), which is the

identical material to the Reference Device Quill™ Synthetic Absorbable Barbed Suture, and the same material acknowledged by the Agency in the FDA Guidance *FDA Special Controls: Application of Class II Surgical Sutures Control Guidance* (see *Section 12, Substantial Equivalence Discussion* of this 510(k) (see *Section 12, Substantial Equivalence Discussion*, **Figure 12-1** of this Premarket Notification).

The technological characteristics the Elevo® Kit Snoring Intervention Device are very similar to the predicate device, as the Subject Device is intended as a treatment option for snoring and consists of an implant and a delivery tool. Like the predicate device, the Subject Device is designed to stiffen the tissue of the soft palate and to reduce the dynamic flutter of those tissues without interfering with the normal function of the soft palate.

The anatomic target location for the Subject Device suture implant is nearly identical to the target location of the predicate device: 5-6 millimeters distal (posterior) to the soft palate/hard palate junction.

The tensile strength of the Elevo® suture implant is comparable to the reference device, as is evidenced by the similar *in vitro* bench test results provided in *Section 12, Substantial Equivalence Discussion*, **Table 12-5** of this Premarket Notification. The force-to-failure test results measured by pull-force testing in bovine material demonstrated that the Elevo® implant suture and the Quill™ PDO Synthetic Absorbable Barbed Suture are equivalent despite the slightly different barb configurations for each device.

The collective clinical safety and efficacy data together with the *in vitro* non-clinical data presented in this Premarket Notification demonstrate that the Elevo® Kit Snoring Intervention Device performs as anticipated, and the device raises no new questions of safety and effectiveness when compared to the predicate device.

The Elevo® Kit Snoring Intervention Device is substantially equivalent to the Pillar™ Palatal Implant System (K118623), which is indicated for use in stiffening the soft palate tissue, and which may reduce the severity of snoring in some individuals.