October 24, 2022

The TMJ Clinic, PC.
John Summer
President
833 SW 11th Ave. # 810
Portland, Oregon 97205

Re: K222127
Trade/Device Name: Soft Palate Elevator
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: July 15, 2022
Received: July 18, 2022

Dear John Summer:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222127

Device Name
SOFT PALATE ELEVATOR

Indications for Use *(Describe)*
TREATMENT OF SNORING

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 SUMMARY - K222127

SUBMITTER AND CONTACT: John Summer, 833 SW 11th Ave # 810, Portland OR 97205
Phone: 503-329-1810 fax: 503-525-2966 Email: john.summer03@gmail.com

DATE PREPARED 7/15/22

DEVICE NAME: SOFT PALATE ELEVATOR

REGULATION NUMBER: 21 CFR 872.5570

REGULATORY CLASS: LRK

CLASSIFICATION: CLASS 2, SPECIAL CONTROLS

GUIDANCE DOCUMENT: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea

NARRATIVE DESCRIPTION

The soft palate elevator consists of an upper base appliance with a palatal plate from which a thin flat metal arm extends posteriorly from its posterior end to terminate in a silicone rubber bulb that raises the center of the soft palate in order to "tent" that flexible structure to draw its distal end upward and forward away from the pharyngeal wall and to tighten the pharyngeal wall. The front end of the arm contains undercut tabs that extend out to the sides to lock into the acrylic in the palatal plate of the base appliance, and the back end of the arm contains features engineered to retain the rubber bulb. The arm is strong enough to elevate the middle of the soft palate about ¼" when it is at rest during sleep and also flexible enough to move up and down with the natural action of the soft palate during swallowing when breathing stops anyway.

MATERIALS – medical silicone, 304 stainless steel, and dental acrylic.

BIOCOMPATIBILITY - the materials in the device have been evaluated for toxic leaching in a variety of use environments and found to be below the threshold for concern, and one final finished subject device was tested for cytotoxicity and found acceptable.

INTENDED USE – to prevent the soft palate from contributing to the airway restrictions that cause snoring.

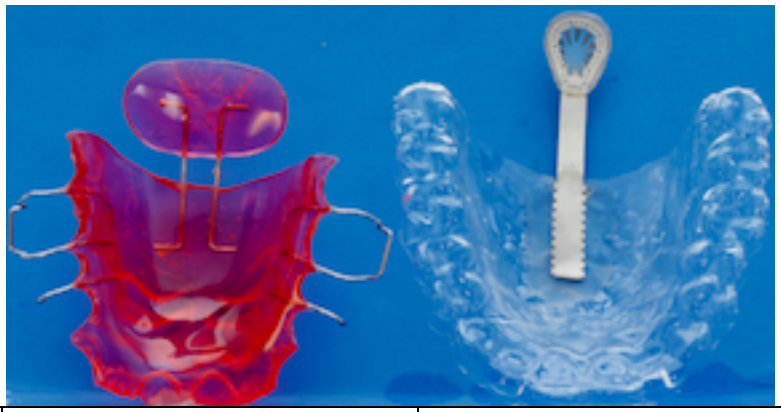
INDICATIONS FOR USE – treatment of snoring.

RISKS – All but one of the risks listed in the guidance document, (damage to the TMJs and oral tissues, including unwanted movement of teeth), are common side effects of mandibular advancement appliances due to the large forces they apply to the teeth and the mandible. The subject device applies much weaker forces (about 2.5 N), and it distributes them between the whole base appliance and the soft palate elevator arm pushing the tissue-contacting bulb up into the center of the soft palate. The risk of damage to the soft palate is mitigated by the softness of the tissue contacting material, the low force it applies, its high biocompatibility, and the easy

adjustability of its supporting arm. The risk of obstructing oral breathing is not affected by the device. The risk of releasing a small part that could cause choking or aspiration is mitigated by retentive features engineered into both ends of the arm, and these retentive features were bench tested to show that they can withstand more force than they will encounter in use. The risk of misuse is primarily from the patient bending the arm it excessively frequently enough to weaken the metal.

PREDICATE - is the adjustable soft palate lifter (K895189), which has the same intended use and indications for use as the subject device. Like the subject device, the predicate employs an arm that extends posteriorly from the posterior end of the palatal plate of an upper base appliance to push upward on the soft palate. Unlike the subject device, the predicate employs a much harder tissue-contacting material and much stronger forces in attempting to raise the entire soft palate. The technological differences between the two devices are presented in table form below.

TECHNOLOGICAL DIFFERENCES



Device	**Predicate device**	**Subject device**
Tissue contacted	Most of soft palate	Midline of soft palate
Tissue-contacting material	Orthodontic acrylic	Silicone rubber
Source of force on tissue contacted	Two .055” diameter stainless steel wires	One .012” x .20” strip of stainless steel

These different technological characteristics of the subject device do not add new safety concerns. In fact, the subject device is likely safer and more effective than the predicate, because its lower forces make it more easily tolerated and safer for the tissues contacted; but the lower forces do not diminish effectiveness, because they are still sufficient to accomplish the intended goal, to raise the center of the soft palate during sleep when it is at rest. Therefore, the subject device is at least as safe and effective as the predicate.

TESTING – Bench testing of both subject device and predicate was accomplished by Engineering Materials Laboratory. Biocompatibility testing of a final finished subject device was performed by Nelson laboratories. Clinical testing was not performed.

BENEFIT/RISK ASSESSMENT – The potential benefit is elimination of snoring and therefore better sleep. An additional potential benefit is preventing damage to and lengthening of the soft palate, which has been demonstrated by imaging in snorers and presumed to be due to the effects of vibration on the tissues, and which can lead to obstructive sleep apnea.[1] The potential risks involve damage to oral tissues and breakage that could cause a part to dislodge and choke the user, - the same benefits and risks produced by the predicate. The subject device was designed with engineered retentive features to reduce the risks of dislodging a part and with lower forces and a softer more biocompatible tissue-contacting surface to prevent tissue damage.

CONCLUSION - The Soft Palate Elevator is similar in intended use and technological characteristics. Based on the performance testing, the Soft Palate Elevator is shown to be substantially equivalent.