July 1, 2021

SnoreBandit LLC
% Colette Cozean
Regulatory Consultant
The EyeDeas Company
21581 Midcrest Dr.
Lake Forest, California 92630

Re: K210910
Trade/Device Name: Snore Bandit
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: May 24, 2021
Received: May 26, 2021

Dear Colette Cozean:

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)*
K210910

Device Name
Snore Bandit Anti-Snoring Appliance

Indications for Use *(Describe)*
Snore Bandit is intended for use by adult patients (18 years or older) as an aid to reduce 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.

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K210910

510(k) Summary

Applicant:	Snore Bandit LLC 8176 Merlewood Ave Las Vegas, NV 89117 Phone: 702-283-3557
Contact person:	Colette Cozean, Ph,D. 21581 Midcrest Dr. Lake Forest, CA 92603 USA 949-855-2885 colettecozean@gmail.com

Date Prepared:	March 24, 2021
Proprietary Name:	Snore Bandit™ Anti-Snoring Appliance
Common name:	Intraoral Device for Snoring
Classification Name:	Device, anti-snoring (Class II, 21 CFR 872.5570, Product Code LRK)
Primary Predicate Device:	Sleep Tight Mouthpiece STZ (K191618)-OTC Reference
Reference Predicate Devices:	Pure Sleep (K190058) – Over the Counter Reference ZQuiet (K180124) – Over the Counter Reference

Description of the Device

The Snore Bandit Anti-Snoring Appliance advances and holds the lower jaw forward during sleep which enlarges and stiffens the airway to alleviate or reduce snoring. The Snore Bandit uses the common 'boil-and bite' technique familiar to athletes who heat and mold their mouth guard to fit their teeth. In this process, the user softens the mouthpiece in hot water according to detailed directions provided with packaging. The user bites into the softened plastic and compresses the softened material to their teeth and gums while holding the jaw slightly forward until the material cools and stiffens. After cooling, the device maintains its shape and is used to hold the jaw open and forward during sleep to alleviate or reduce snoring. The product is non-sterile and provided in a sealed box with instructions.

Indications for Use

Snore Bandit is intended for use by adults (18 years or older) as an aid to reduce snoring.

A. Technological Characteristics

The appliance is equivalent in design and functionality to the primary predicate, Sleep Tight Mouthpiece (STZ) device (K191618). Both devices work by advancing the mandible and allows the patient to breathe through their mouth and nose utilizing space between the upper and lower teeth. Both are custom fit for comfort to the individual user by a standard 'boil and bite' method. Both use an ethylene vinyl acetate material. Both are manufactured via a molding process. Both devices are provided non-sterile. The main difference between the subject device and the primary predicate device is a multi-layered breathing space design rather than a single-layer breathing space design in the primary predicate device. This opens the airway and allows maximum airflow and prevents the patient's lips from blocking the breathing ports.

Comparison to Predicate Devices

	Subject	**OTC Primary Predicate**	**OTC Reference Predicate**	**OTC Reference Predicate**
Name	Snore Bandit	STZ	PureSleep	ZQuiet
Classification name	Device, anti-snoring	Device, anti-snoring	Intraoral Device for Snoring and Obstructive Sleep Apnea	Device, anti-snoring
510(k) Number	K210910	K191618	K190058	K180124
Class	II	II	II	II
Product Code	LRK	LRK	LRK	LRK
21 CFR	872.5570	872.5570	872.5570	872.5570
Technology & Mechanism of Action	Mandibular advancement design to increase pharyngeal space to alleviate snoring	Mandibular advancement	Mandibular repositioning device (MRD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular advancement

Indications for use	"Snore Bandit is intended for use on adults 18 years of age or older as an aid to reduce snoring"	"Sleep Tight Mouthpiece STZ is intended for use on adult patients 18 years of age or older as an aid to reduce snoring"	Adults	"ZQuiet is intended as an aid in the reduction of snoring for adults at least 18 years old."
Prescription Status	OTC	OTC	OTC	OTC
Provided Sterile	NO	NO	NO	NO
Materials	Ethylene Vinyl Acetate (EVA) Copolymer, no colorant	Thermoplastic Elastomer (Ethyl Vinyl Acetate)	Polypropylene homopolymer and Ethylene Vinyl Acetate (EVA)	Thermoplastic Elastomer with a colorant

B. Technology - Mechanism of Action

The subject device and primary predicate device (K191618) are identical in the mechanism of action. They both work by utilizing an intraoral mouthpiece to advance the lower mandible and create space between the upper and lower teeth (breathing spaces) giving the patient the ability to breathe through their mouth and nose.

The mechanism of action for the other two OTC reference predicate devices, the PureSleep and ZQuiet, is solely advancing the mandible. With an intraoral device that alters the mandible position, mandibular changes can lead to pain or discomfort in the temporomandibular joint (TMJ). The subject device has no new risks regarding mandibular advancement.

Utilizing the same mechanism of action as the predicate devices (primary and reference), the subject device raises no new concerns regarding the effectiveness or safety as compared to the other predicate devices.

C. Indication for Use

The subject device uses language for the indication for use in substance to previously approved OTC devices for the reduction of snoring. The subject device is "intended for use by adults (18 years or older) as an aid to reduce snoring."

This is almost identical to the indications for use for the primary predicate devices, and the two reference devices, the Sleep Tight Mouthpiece (STZ) is intended for use by adult patients 18 years of age as an aid to reduce snoring, PureSleep is an intraoral mandibular repositioning device used on adults as an aid during sleep to reduce snoring and ZQuiet, whose indications is "intended as an aid in the reduction of snoring for adults at least 18 years old" respectively.

As the indications for use are identical, there are no new concerns regarding safety as compared to predicate devices (primary and reference).

D. Prescription Status

The subject device is intended to be sold over-the-counter. All of the predicate devices (primary and reference), STZ, PureSleep, and ZQuiet have clearance for over-the-counter use. The subject labeling specifically states that the device does not treat obstructive sleep apnea and the STOP-BANG questionnaire is included in the labeling to help mitigate the risk of undiagnosed OSA among potential Snore Bandit users.

Substantial equivalent labeling and instructions for use to that of the over-the-counter predicate devices, there are no new concerns regarding effectiveness or safety as compared to predicate devices (primary and reference).

E. Labeling

The subject appliance has similar labeling as the OTC reference predicate devices (primary and reference), Sleep Tight Mouthpiece (STZ), PureSleep, and ZQuiet. It utilizes a validated questionnaire to access the risk of sleep apnea and contains the appropriate warnings and labeling for the device to be used without requiring a prescription.

F. Technology – Materials

To support this application, the sponsor has included Biocompatibility testing results demonstrating the subject device is biocompatible under ISO 10993, including cytotoxicity, sensitization, and irritation testing. The device was shown to meet the requirements of the ISO 10993 guidelines for each of these tests. Other biocompatibility tests recommended for permanent mucosal contact were not conducted because all materials used in the device are certified USP Class VI and used in many other currently marketed medical devices, including another mouthguard called Somnos Anti-Snoring Mouth Guard (K201484) made by the same manufacturer that makes Snore Bandit.

Because the same materials and manufacturing processes are used in the primary predicate device, there are no new concerns regarding effectiveness or safety as compared to the predicate devices.

G. Biocompatibility

The materials and manufacturing process are similar to the predicate devices (primary and reference). One hundred percent of the Snore Bandit is made of Elvax. There is no added colorant in Snore Bandit.

Testing results have been included include cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation (ISO 10993-10). As all the materials used in the device are certified USP Class VI and used in many other currently marketed medical devices, no additional biocompatibility testing was conducted.

Clinical Testing

No clinical testing was performed in association with this submission.

Conclusions

The results of the comparison of design, materials, intended use, labeling, and technological characteristics demonstrate the subject device is substantially equivalent in safety and efficacy to the legally marketed predicate devices, both the primary and reference predicates. Therefore, the sponsor concludes the proposed Snore Bandit device is substantially equivalent to the identified predicate devices.