December 2, 2022

Shinrin-Yoku Traders LLC
℅ Ryan Bruss
Regulatory Consultant
RGLM Consulting LLC
6915 225th St SW
Mountlake Terrace, Washington 98043

Re: K220688
Trade/Device Name: SilentZPro 2.0
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 4, 2022
Received: November 4, 2022

Dear Ryan Bruss:

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,

Bobak Shirmohammadi -S

For 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)*
K220688

Device Name
SilentZPro 2.0

Indications for Use *(Describe)*
SilentZPro 2.0 is intended as an aid in the reduction of snoring for adults at least 18 years old.

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

Device Name: SilentZPro 2.0

A. General Information

Sponsor	Shinrin-Yoku Traders LLC 18450 SW Seiffert Rd, Sherwood, OR 97140
Contact Person	Ryan Bruss CEO Tel: 971-712-9175 Email: shinrinyokutradersllc@gmail.com
K Number	K220688
Date prepared	November 3, 2022

B. Device

Propriety Name	SilentZPro 2.0
Common Name	Antisnoring device
Classification Name	Intraoral devices for snoring and obstructive sleep apnea
Product Code	LRK
Class	II
Regulation Number	21 CFR 872.5570

C. Predicate Device

Name	PureSleep®
Owner	Sleep Science Partners, Inc.
K number	K190058

Reference Device: SnoreRx® (K170825, Apnea Sciences, Inc.)

D. Description of the Device

SilentZPro 2.0 is an intraoral device composed of a maxillary and mandibular tray assembled to position the mandible forward relative to the maxilla to increase users' pharyngeal space and improve the ability to exchange air and decreases air turbulence, a causative factor in snoring.

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The device is intended for Over-the-Counter (OTC) use.

E. Intended Use Statement

SilentZPro 2.0 is intended as an aid in the reduction of snoring for adults at least 18 years old.

F. Comparison of Technological Characteristics

The table below compares the similarities and differences between the SilentZPro 2.0 and the predicate device/Reference device.

Attribute	Proposed device (K220688)	Predicate device (K190058)	Reference device (K170825)
Proprietary Name	SilentZPro 2.0	PureSleep®	SnoreRx®
Manufacturer	Shinrin-Yoku Traders LLC	Sleep Science Partners, Inc.	Apnea Sciences, Inc.
510k Number	K220688	K190058	K170825
Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570
Product Code	LRK	LRK	LRK
Class Name	Same	Intraoral Device for Snoring and Obstructive Sleep Apnea	Same
Rx or OTC	OTC	OTC	OTC
Intended Use	SilentZ Pro 2.0 is intended as an aid in the reduction of snoring for adults at least 18 years old.	PureSleep® (OTC) is indicated for use for adults 18 years and above as an aid in the reduction of snoring during hours of sleep	The SnoreRx is intended for use on adult patients 18 years of age or older as an aid for the reduction of snoring.
Population	Same	Adult	Same
Environment	Same	During sleep, at home	Same
Mechanism of action	Same as the Predicate Device	Mandibular repositioning device (MRD) that advances the lower jaw to increase pharyngeal space and alleviate snoring	Mandibular repositioning device that advances the lower jaw to increase pharyngeal space.

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Attribute	Proposed device (K220688)	Predicate device (K190058)	Reference device (K170825)
Placement of device	In the mouth, on the lower and upper jaws	In the mouth, on the lower and upper jaws	In the mouth, on the lower and upper jaws
Preparation / Set-up	Same as reference device. (Squeeze mouthpiece in a "c" position and adjust. Mold the trays to the user's mouth.)	Connect upper and lower parts per user comfort. Mold the trays to the user's mouth.	Squeeze mouthpiece in a 'C' position and adjust. Mold tray Mold the trays to the user's mouth.
Design	Custom-fitted intraoral device using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth. Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus allows for custom fitting.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth. Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus allows for custom fitting.	Custom impression to each individual's mouth using a "boil and bite" approach and thermal setting (heat sensitive) resins. Molded to the entire upper and lower arch of teeth. Consists of an upper and lower tray. Outer shell provides with structural support and inner shell is lined with softer material that is heat sensitive and thus allows for custom fitting.
Adjustments	Adjustable jaw advancement position. Adjustably positions the mandible forward in 3 positions, 4mm apart anteriorly, while maintaining a 9mm inferior placement for user comfort	Adjustable jaw advancement position. Adjustably positions the mandible forward in three positions, 4mm apart anteriorly, while maintaining a 9mm inferior placement for user comfort	Adjustable jaw advancement position. Ability to reset the adjustment. The upper and lower trays are adjustable in 1mm increments up to 6mm.
Single Patient/ Reusable	Single user, reusable. Non-sterile. Requires daily cleaning, and reusable with a life use of no more than 30 days.	Single user, reusable. Clean/rinse daily with toothbrush and toothpaste or with effervescent oral device cleaning tablets. Deep clean once per week. Non-sterile.	Clean/rinse daily. Deep clean every two weeks. Non-sterile.
Materials	Same as the Reference Device	Polypropylene homopolymer; ethylene vinyl acetate copolymer (EVA)	Polycarbonates (PC); Ethylene-vinyl acetate copolymer resin (EVA)

Attribute	Proposed device (K220688)	Predicate device (K190058)	Reference device (K170825)
Biocompatibility	Same	Assessment conducted for testing for prolonged mucosal surface contact in accordance with ISO 10993-1.	Same

The SilentZPro 2.0 has the same general intended use as the predicate device, and the similar technological characteristics as the predicate device. The biocompatibility performance of the SilentZPro 2.0 met the standard of ISO 10993 biocompatibility testing. The materials of SilentZPro 2.0 are the same as the reference device. The differences between the SilentZPro 2.0 and the predicate device do not raise different questions of safety and effectiveness.

G. Performance Testing

Non-Clinical Testing

Testing results have been included include cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation (ISO 10993-10). The results of the testing demonstrated that the subject device is biocompatible and meets the applicable requirements of ISO 10993.

Device materials were tested for various physical properties.

Shinrin-Yoku Traders LLC conducted a risk analysis on SilentZPro 2.0 in accordance with ISO 14971:2007 and the FDA guidance document “Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea”. All identified risks have been addressed through device design, biocompatibility tests or through labeling provided to the consumer.

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Clinical Performance Testing

No clinical performance testing was conducted.

Risk Analysis

Shinrin-Yoku Traders LLC conducted a risk analysis on SilentZPro 2.0 in accordance with ISO 14971:2007 and the FDA guidance document "Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea" (November 12, 2002). All identified risks have been addressed through device design, biocompatibility tests or through labeling provided to the consumer.

H. Conclusions

Based on the similarities in intended use and indications for use, together with technologic similarities and results of performance testing, we believe that SilentZPro 2.0 is substantially equivalent to the predicate device, PureSleep® .