October 6, 2022

ProSomnus Sleep Technologies
Divya Mavalli
Director of Regulatory & Quality
5860 W Las Positas Blvd.
Suite 25
Pleasanton, California 94588

Re: K221889
Trade/Device Name: ProSomnus EVO [PH] Sleep and Snore Device, ProSomnus EVO [PH] Sleep and Snore Device with Patient Monitoring
Regulation Number: 21 CFR 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, LQZ, PLC
Dated: August 26, 2022
Received: August 29, 2022

Dear Divya Mavalli:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221889

Device Name
ProSomnus® EVO™ [PH] Sleep and Snore Device
ProSomnus® EVO™ [PH] Sleep and Snore Device with Patient Monitoring

Indications for Use *(Describe)*
The ProSomnus® EVO™ [PH] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Optionally, if the DentiTrac micro-recorder is completely embedded in the ProSomnus® EVO™ [PH] Sleep and Snore Device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.

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 - K221889

1. Manufacturer and Submitter

Company Name:	ProSomnus Sleep Technology, Inc.
Company Address:	5860 West Las Positas Blvd. Suite 25 Pleasanton, CA 94588
Contact Person:	Divya Mavalli Email: dmavalli@prosomnus.com Phone: 925.307.5337
Date Prepared:	August 30, 2022

2. Device Name and Classification

Trade/Proprietary Name:	ProSomnus® EVO™ [PH] Sleep and Snore Device ProSomnus® EVO™ [PH] Sleep and Snore Device with Patient Monitoring
Common Name:	Mandibular Advancement Device
Classification Name: and	Intraoral devices for snoring and intraoral devices for snoring obstructive sleep apnea.
Regulatory Class:	II (special controls)
Regulatory Number:	21 CFR 872.5570
Product Code:	LRK (Device, Anti-snoring), LQZ (Device, Jaw Repositioning), and PLC (Sleep Appliances with Patient Monitoring)
Panel:	Dental

3. Predicate and Reference Devices

Device Names:	Kava and Kava with Herbst Respire Pink Series with DentiTrac
510(k) Numbers:	K182661 K170692

4. Device Description

The ProSomnus® EVO™ [PH] Sleep and Snore Device consists of maxillary and mandibular device arches that when interfaced together reduce snoring and mild to moderate obstructive sleep apnea by holding the mandible forward during sleep, providing increased pharyngeal space. These separate upper and lower device arches are connected with the herbst advancer. The device is designed and manufactured using Computer Aided Design/Computer Aided Manufacturing (CAD/CAM) dental technologies, which allows the delivery of a well-fitting, aesthetic, and durable intraoral device for the patient. These devices are digitally milled to be patient-specific according to physician prescription. Prescribed advancements can be achieved by simply rotating the telescopic advancer hex nut or pinhole mechanism in an upward direction to increase the forward positioning of the mandible by smaller increments and according to the physician schedule. Advancements up to 12 mm past the initial bite position may be achieved with additional arches as prescribed by the physician The patient will be able to move the lower jaw forward, side-to-side, and open and close the mouth while wearing the device. The proposed device materials include medical grade polymer, stainless steel herbst arms, and biocompatible adhesive. The device is supplied nonsterile.

5. Intended Use/Indication for Use

The ProSomnus® EVO™ [PH] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Optionally, if the DentiTrac micro-recorder is completely embedded in the ProSomnus® EVO™ [PH] Sleep and Snore Device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.

6. Non-Clinical Performance Data

Product performance testing was performed to support the above indications for use as well as the claim of Substantial Equivalence.

Bench testing of the ProSomnus® EVO™ [PH] Sleep and Snore Device was conducted in accordance with ProSomnus Sleep Technologies' risk analysis and all applicable FDA guidance documents and international standards, including:

ISO 10993-1, Biological evaluation of medical device – Part 1 Evaluation and testing within a risk management process

ISO 10993-5 - Biological evaluation of medical device – Part 5 Tests for in vitro cytotoxicity

ISO 10993-10 – Biological evaluation of medical device – Part 10 Tests irritation and skin sensitization

ISO 10993-11 – Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

ISO 10993-12 – Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

ISO 10993- 23 Biological evaluation of medical devices – Part 23: Tests for irritation

ISO 14971 Medical devices - Application of risk management to medical devices

Guidance for industry and FDA Staff: Class II Special Controls Intraoral Devices for Snoring and/or Obstructive Sleep Apnea

Bench testing was conducted on finished devices, unless otherwise specified. The following testing was completed:

- Metal-Free Button Hook Strength Testing
- Shear Testing
- Loctite 3922 Cure Time Test
- Polymer Adhesive Pull Test

Packaging

Packaging distribution testing was performed following ASTM D4169 procedure, following Distribution Cycle 13 at Assurance Level II.

Biocompatibility

Biocompatibility testing, per ISO 10993-1 was performed, which included the following tests: Cytotoxicity, Sensitization, and Irritation

Physical Properties Testing

Modulus of elasticity (tensile test)	ASTM D 638
Tensile strength at yield	ASTM D 638
Elongation at break (tensile test)	ASTM D 638
Flexural strength	ASTM D 790
Modulus of elasticity (flexural test)	ASTM D 790
Compression strength	ASTM D 695
Compression modulus	ASTM D 790
Notched impact strength (Izod)	ASTM D 256
Rockwell hardness	ASTM D 785
Deflection temperature	ASTM D 648
Moisture absorption	ASTM D 570

7. Comparison of Technological Characteristics

The ProSomnus® EVO™ [PH] Sleep and Snore Device has the same intended use as the predicate and reference devices. The materials, design, and performance characteristics are similar to the predicate and reference devices.

The below table provides a comparison of technological characteristics to predicate and reference devices.

Characteristics	ProSomnus® EVO™ [PH] Sleep and Snore Device **(Subject Device)**	Kava and Kava with Herbst **(Predicate Device)**	Respire Pink Series with DentiTrac **(Reference Device)**
Body Material	Medical Grade Polymer	Polymethyl methacrylate (PMMA)	Polymethyl methacrylate (PMMA)
Usability	Single-patient, multiple use	Single-patient, multiple use	Single-patient, multiple use
Splint	Comprised of two customizable splints (upper and lower)	Comprised of two splints (upper and lower)	Comprised of two splints (upper and lower)
Splints Jointure	Herbst style adjustable medical grade stainless steel advancement mechanism	Adjustable metal screws or lugs	Surgical grade stainless steel herbst hardware
Technical Method	Advances the patient's mandible in a forward position to increase airway space. Optionally, monitors patient's compliance to the oral appliance therapy.	Advances the patient's mandible in a forward position to maintain an open airway.	Advances the patient's mandible in a forward position to maintain an open airway. Optionally, monitors the patient compliance to oral appliance therapy.
Embed Micro-Recorder	Optional	No	Optional

8. Substantial Equivalence

Substantially Equivalent Connection	**ProSomnus® EVO™ [PH] Sleep and Snore Device (Subject Device)**	Kava and Kava with Herbst **(Predicate Device)**	Respire Pink Series with DentiTrac **(Reference Device)**
510(k) Number	K221889	K182661	K170692
Manufacturer	ProSomnus Sleep Technologies	Sketchpad Innovations LLC	Respire Medical Holding
Relation	Subject Device	Predicate Device	Reference Device with Patient Monitoring
Device	• Device, Anti-Snoring • Device, Jaw Repositioning • Sleep Appliances with Patient Monitoring	• Device, Anti-Snoring • Device, Jaw Repositioning	Sleep Appliances with Patient Monitoring
Product Code	LRK LQZ PLC	LRK LQZ	PLC
Device Classification	Class II	Class II	Class II
Regulation Number	21 CFR 872.5570	21 CFR 872.5570	21 CFR 872.5570

Indications for Use	The ProSomnus® EVO™ [PH] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. Optionally, if the DentiTrac micro-recorder is completely embedded in the ProSomnus® EVO™ [PH] Sleep and Snore Device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.	The Kava and Kava with Herbst device(s) are intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The Respire Pink Series intraoral appliances are intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally, the DentiTrac micro-recorder may be incorporated into a Respire Pink Series device. The micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac system.
Usability	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use
Target Population	Adult patients	Adult patients	Adult patients
Where Used	For personal nighttime use at home or in sleep laboratories	For personal use	For personal use
Biocompatible	Yes	Yes	Yes
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Prescription	Yes	Yes	Yes
Principle of Operation	Mandibular Repositioners	Mandibular Repositioners	Mandibular Repositioners
Non-Sterile	Yes	Yes	Yes
Design	Allows mandibular movement and to open and close mouth during wear.	Allows mandibular movement and to open and close mouth during wear.	Allows mandibular movement and to open and close mouth during wear.

Adjustment Mechanism	Herbst style advancement	Herbst style advancement	Herbst style advancement
Clean	Daily	Daily	Daily

9. Conclusion

The ProSomnus® EVO™ [PH] Sleep and Snore Device is substantially equivalent to the predicate device with respect to safety and effectiveness.