November 20, 2020

ProSomnus Sleep Technologies, Inc.
Divya Mavalli
Quality and Regulatory Manager
5860 West Las Positas Blvd.
Pleasanton, California 94588

Re: K202529
Trade/Device Name: ProSomnus EVO Sleep and Snore Device, ProSomnus EVO Sleep and Snore Device with Patient Monitoring
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, LQZ, PLC
Dated: October 23, 2020
Received: October 26, 2020

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*
K202529

Device Name
ProSomnus® EVO Sleep and Snore Device
ProSomnus® EVO Sleep and Snore Device with Patient Monitoring

Indications for Use *(Describe)*
The ProSomnus® EVO 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 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.

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K202529

510(K) SUMMARY

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:	October 23, 2020

2. Device Name and Classification

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

3. Predicate Device

Device Name:	ProSomnus® MicrO2 Obstructive Sleep Apnea Device
510(k) Number:	K133683

Reference Device

Device Name:	ProSomnus® MicrO2 Obstructive Sleep Apnea Device with Micro-Recorder

510(k) Number: K161624

4. Device Description

The ProSomnus® EVO Sleep and Snore Device is an oral device, which improves the flow of air through the patient's pharyngeal space during sleep by repositioning the mandible. The ProSomnus® EVO Sleep and Snore Device and the ProSomnus® EVO Sleep and Snore Device with Patient Monitoring consists of maxillary and mandibular devices 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 CAD/CAM designed with twin-mated posts and are digitally milled to be patient-specific according to physician prescription. Customizable ergonomic features are available to improve patient comfort. Prescribed advancements can be achieved by simply removing the current upper or lower device arch and inserting the next upper or lower device arch in the mandibular advancement series. The device does not have any adjustment mechanisms to modify or maintain the mandibular position such as pistons, screws, straps, or repositioning elastics. The device is supplied nonsterile.

A micro-recorder is completely embedded in the ProSomnus® EVO Sleep and Snore Device with Patient Monitoring. The micro-recorder is a compliance sensor, which logs the time the device is worn.

5. Intended Use/Indication for Use

The ProSomnus® EVO 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 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. Technological Characteristics

Both the predicate and subject devices use upper and lower device arches to reposition the mandible.

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

Characteristics	ProSomnus® EVO Sleep and Snore Device (Subject Device)	ProSomnus® EVO Sleep and Snore Device with Patient Monitoring	ProSomnus MicrO2 Obstructive Sleep Apnea Device	ProSomnus MicrO2 Obstructive Sleep Apnea

		(Subject Device with Micro-Recorder)	(Predicate Device)	Device with Micro-Recorder (Reference Device)
Body Material	Medical Grade Polymer	Medical Grade Polymer	Polymethyl methacrylate (PMMA)	Polymethyl methacrylate (PMMA)
Usability	Single-patient, multiple use	Single-patient, multiple use	Single-patient, multiple use	Single-patient, multiple use
Splint	Comprised of two or more customizable splints (upper and lower)	Comprised of two or more customizable splints (upper and lower)	Comprised of two or more customizable splints (upper and lower)	Comprised of two or more customizable splints (upper and lower)
Technical Method	Advances the patient's mandible in a forward position to increase airway space	Advances the patient's mandible in a forward position to increase airway space and additionally monitors the patient compliance to oral appliance therapy	Advances the patient's mandible in a forward position to increase airway space	Advances the patient's mandible in a forward position to increase airway space and additionally monitors the patient compliance to oral appliance therapy
Ergonomic Features – Splint Design	The scalloped and contoured edge allows for patient comfort	The scalloped and contoured edge allows for patient comfort	Straight-line plane at the edge of the splint around the front of the teeth	Straight-line plane at the edge of the splint around the front of the teeth
Ergonomic Features – Post Style	The dual radius posts to allow for patient comfort	The dual radius posts to allow for patient comfort	The post angle to the splint is a standard 90 degrees	The post angle to the splint is a standard 90 degrees
Ergonomic Features – Anterior Airway	Anterior airway opening	Anterior airway opening	No anterior airway opening	No anterior airway opening

Ergonomic Features – Anterior Discluder	The prescribing provider can request the addition of a vertical element	The prescribing provider can request the addition of a vertical element	No discluder option is provided	No discluder option is provided
Ergonomic Features – Lingual Coverage	Prescriber may request posterior or full lingual coverage	Prescriber may request posterior or full lingual coverage	No posterior or full lingual coverage provided	No posterior or full lingual coverage provided
Ergonomic Features – Plastic Hooks	Plastic hooks incorporated into the design	Plastic hooks incorporated into the design	Uses stainless steel balls or hooks to secure rubber bands in those prescriptions where they are indicated	Uses stainless steel balls or hooks to secure rubber bands in those prescriptions where they are indicated

7. Performance Data

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

Performance Specification	Subject Device ProSomnus® EVO Sleep and Snore Device	Predicate Device ProSomnus MicrO2 OSA Device	Acceptance Criteria	Results (Pass/Fail)
Anterior-Posterior (AP) Shear Strength (lbf)	235.4	239.8	Must be greater than 200 lbf	Pass
Stroke (in)	0.17	0.11	Must be greater than 0.1	Pass
Anterior-Posterior Directional Torque (lbf-in)	235.4 lbf * 0.17 in = 40.0 lbf-in	239.8 lbf * 0.11 in = 26.4 lbf-in	Must be equal or better than predicate device	Pass
Lateral Direction Shear Strength (lbf)	71.5	94.2	Must be greater than 50 lbf	Pass

Stroke (in)	0.17	0.11	Must be greater than 0.1	Pass
Lateral Directional Torque (lbf-in)	71.5 lbf * 0.17 in = 12.2 lbf-in	94.2 lbf * 0.11 in = 10.4 lbf-in	Must be equal or better than predicate device	Pass
Durability when elastic bands pull on hooks at peak forcé (mm & lbs.)	135.55 mm stretch length with an average peak forcé of 5.06 lbs. With no visible damage to the device and its metal-free hooks.	135.55 mm stretch length with an average peak forcé of 4.74 lbs. With no visible damage to the device and its metal-free hooks.	Must be equal or more durable then predicate device	Pass

Non-Clinical Performance Testing

Product biocompatibility testing and risk analysis were performed, and the following standards were utilized:

- ISO 10993-1: 2018 Biological Evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-2 Second edition 2006-07-15 Biological Evaluation of medical devices - Part 2: Animal welfare requirements
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 7405: 2018 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices

8. Substantial Equivalence

Substantially Equivalent Connection	ProSomnus® EVO Sleep and Snore Device	ProSomnus® EVO Sleep and Snore Device with Patient Monitoring	ProSomnus MicrO2 Obstructive Sleep Apnea Device	ProSomnus MicrO2 Obstructive Sleep Apnea Device with Micro-Recorder
510(k) Number	K202529	K202529	K133683	K161624
Manufacturer	ProSomnus Sleep Technologies	ProSomnus Sleep Technologies	ProSomnus Sleep Technologies	ProSomnus Sleep Technologies
Relation	Subject Device	Subject Device with Patient Monitoring	Predicate Device	Predicate Device with Micro-Recorder
Device	Device, Anti-Snoring Device, Jaw Repositioning	Sleep Appliances with Patient Monitoring	Device, Anti-Snoring	Sleep Appliances with Patient Monitoring
Product Code	LRK LQZ	PLC	LRK	PLC
Indications for Use	The device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Usability	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use	Single patient, multiple use
Target Population	Adult patients	Adult patients	Adult patients	Adult patients
Where Used	For personal use at home or in sleep laboratories	For personal use at home or in sleep laboratories	For personal use at home or in sleep laboratories	For personal use at home or in sleep laboratories
Prescription	Yes	Yes	Yes	Yes
Principle of Operation	Mandibular Repositioners	Mandibular Repositioners	Mandibular Repositioners	Mandibular Repositioners
Non-Sterile	Yes	Yes	Yes	Yes

Design	Allows space for tongue and mandibular movement of mouth opening and closing during wear	Allows space for tongue and mandibular movement of mouth opening and closing during wear	Allows space for tongue and mandibular movement of mouth opening and closing during wear	Allows space for tongue and mandibular movement of mouth opening and closing during wear
Adjustment Mechanism	No adjustment mechanisms such as pistons, screws, straps, or repositioning elastics are used to modify or maintain the mandibular position	No adjustment mechanisms such as pistons, screws, straps, or repositioning elastics are used to modify or maintain the mandibular position	No adjustment mechanisms such as pistons, screws, straps, or repositioning elastics are used to modify or maintain the mandibular position	No adjustment mechanisms such as pistons, screws, straps, or repositioning elastics are used to modify or maintain the mandibular position

9. Conclusion

Based on the comparison of technology and the indications for use, we find that ProSomnus® EVO Sleep and Snore Device is substantially equivalent to ProSomnus® MicrO2 Obstructive Sleep Apnea Device.