Prosomnous Sleep Technologies
David Kuhns
VP of Technology
5860 W. Las Positas Blvd., Suite 25
Pleasanton, California 94588

November 22, 2017

Re: K172859
Trade/Device Name: Prosomnus [CA] Sleep and Snore Device and Prosomnus [CA] Sleep and Snore Device with Micro-recorder
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: PLC, LRK
Dated: November 3, 2017
Received: November 6, 2017

Dear David Kuhns:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K172859

Device Name
Prosomnus [CA] Sleep and Snore Device

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K172859

Device Name
Prosomnus [CA] Sleep and Snore Device with Micro-recorder

Indications for Use *(Describe)*
The Prosomnus [CA] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
The DentiTrac® micro-recorder is completely embedded into the Prosomnus [CA] Sleep and Snore appliance. The micro-recorder is intended to measure patient compliance to the oral 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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Prosomnus [CA] Sleep and Snore Device
510(k) Summary – K172859
November 2017

1. Company:

Prosomnus Sleep Technologies
5860 West Las Positas Blvd., Suite 25,
Pleasanton, CA 94588

Contact: David Kuhns
VP of Technology
Phone: (925)803-8643
regulatory@prosomnus.com

Date Summary Prepared: November 16, 2017

2. Proprietary Trade Name: Prosomnus [CA] Sleep and Snore Device

3. Common Name: Intraoral appliance for snoring and obstructive sleep apnea

4. Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

5. Product Code: LRK (Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.)

6. Primary Predicate: MicrO2 OSA Device K133683

Reference Device: SomnoDent Fusion K140278

Reference Device: Narval CC K113201

7. Product Description: The Prosomnus [CA] Sleep and Snore device consists of maxillary and mandibular devices that when interfaced together reduce snoring and mild to moderate sleep apnea by holding the mandible forward during sleep, providing increased pharyngeal space. These separate upper and lower arch devices are designed with twin-mated posts and are CAD/CAM generated specifically for each prescription. Designed as a patient-specific device, the Prosomnus [CA] Sleep and Snore device series consists of one or multiple lower device(s) together with one or multiple mated-post upper device(s) that are manufactured to the dentist prescriber's requested advancement positions up to 11mm to provide a selection of gentle adjustments according to patient comfort and need. As such, prescribed advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series. The Prosomnus [CA] Sleep and Snore device twin-mated post and lingualess design yields a small and a comfortable patient-specific mandibular advancement device. The design of the device maximizes tongue space and mandibular movement resulting in the ability to open and close during wear.

This submission adds the option for an embedded screw that allows for smaller discreet movements of the mandible in between the lower arch advancements. The inclusion of the embedded screw does not change the intended use, impact the operating principles nor impact the fundamental scientific principles of the device as established by the predicate device K133683, the MicrO2 OSA device. The same principles of operation to move the mandible forward are used to increase pharyngeal space and maximize the tongue space.

8. **Indications for Use:** The Prosomnus [CA] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

9. **Substantial Equivalence:** Documentation that includes a performance assessment and detailed comparison to the predicate device demonstrates that the Prosomnus [CA] Sleep and Snore Device is substantially equivalent to the following 510(k) cleared device:

Trade Name: MicrO2 OSA Device
Common Name: Intraoral appliance for snoring and obstructive sleep apnea
510(k) Clearance Number: K133683
Indications for Use: The MicrO2 Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Reference Device:
Trade Name: SomnoDent Fusion
Common Name: Intraoral appliance for snoring and obstructive sleep apnea
510(k) Clearance Number: K140278 (LRK product code without compliance chip)

Reference Device:
Trade Name: Narvall CC
Common Name: Intraoral appliance for snoring and obstructive sleep apnea
510(k) Clearance Number: K113201

Substantial equivalence is based on identical indications for use, technological characteristics and *in vitro* testing performed. The Risk Management file was updated to include the design modifications and no new risks were identified.

The device with embedded screws that are subject of this premarket notification and the predicate device have the same indications for use. Specifically, both the predicate MicrO2 OSA Device and the Prosommus [CA] Sleep and Snore Device that is subject of this Traditional 510(k) is indicated for nighttime snoring and mild to moderate sleep apnea in adults. The option of the compliance chip is available in the same fashion as in the MicrO2 OSA Device. No changes are being made to the materials, technological characteristics or principles of operation as a result of this premarket notification. Both devices are inserted into the mouth and are adjusted or exchanged according to physician prescription. The differences between the subject device and the predicate device are as follows although these modifications are identical to the reference predicate as noted above.:

- Embedded screw

- Patient locking key

The digital milling manufacturing process and material are the same. Data relied upon to determine substantial equivalence of the Prosomnus [CA] Sleep and Snore device with the device modifications described in this submission to the cleared MicrO2 OSA device include the following:

Test Description
Compression and Shear Torsion Testing
Package and Distribution Testing

There are no changes being made to the digitally milling manufacturing process as a result of this submission.

Conclusions can be drawn from the tests that the modifications to the Prosomnus [CA] Sleep and Snore Device are substantially equivalent and meet the performance specifications.

Prosomnus [CA] Sleep and Snore Device
510(k) Summary – K172859
November 2017

1. Company:

Prosomnus Sleep Technologies
5860 West Las Positas Blvd., Suite 25,
Pleasanton, CA 94588

Contact: David Kuhns
VP of Technology
Phone: (925)803-8643
regulatory@prosomnus.com

Date Summary Prepared: November 16, 2017

2. Proprietary Trade Name: Prosomnus [CA] Sleep and Snore Device with Micro-recorder

3. Common Name: Intraoral appliance for snoring and obstructive sleep apnea

4. Classification Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

5. Product Code: PLC (Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea with patient compliance monitoring.)

6. Primary Predicate: MicrO2 Sleep and Snore Device with Micro-recorder K161624

Reference Device: SomnoDent (Fusion) with Micro Recorder K150369

Reference Device: Narval CC K113201

7. Product Description: The Prosomnus [CA] Sleep and Snore device consists of maxillary and mandibular devices that when interfaced together reduce snoring and mild to moderate sleep apnea by holding the mandible forward during sleep, providing increased pharyngeal space. These separate upper and lower arch devices are designed with twin-mated posts and are CAD/CAM generated specifically for each prescription. Designed as a patient-specific device, the Prosomnus [CA] Sleep and Snore device series consists of one or multiple lower device(s) together with one or multiple mated-post upper device(s) that are manufactured to the dentist prescriber's requested advancement positions up to 11 mm to provide a selection of gentle adjustments according to patient comfort and need. As such, prescribed advancements can be achieved by simply removing the current upper or lower device and inserting the next upper or lower device in the mandibular advancing series. The Prosomnus [CA] Sleep and Snore device twin-mated post and lingualess design yields a small and a comfortable patient-specific mandibular advancement device. The design of the device maximizes tongue space and mandibular movement resulting in the ability to open and close during wear. The Prosomnus [CA] Sleep and Snore device includes an optional Micro-recorder to monitor patient compliance.

This submission adds the option for an embedded screw that allows for smaller discreet movements of the mandible in between the lower arch advancements. The inclusion of the embedded screw does not change the intended use, impact the operating principles nor impact the fundamental scientific principles of the device as established by the predicate device K161624, the Prosomnus MicrO2 OSA device with micro-recorder. The same principles of operation to move the mandible forward are used to increase pharyngeal space and maximize the tongue space.

8. **Indications for Use:** The Prosomnus [CA] Sleep and Snore Device is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

   The DentiTrac® micro-recorder is completely embedded into the Prosomnus [CA] Sleep and Snore appliance. The micro-recorder is intended to measure patient compliance to the oral appliance therapy in combination with the DentiTrac® System.

9. **Substantial Equivalence:** Documentation that includes a performance assessment and detailed comparison to the predicate device demonstrates that the Prosomnus [CA] Sleep and Snore Device is substantially equivalent to the following 510(k) cleared device:

   Trade Name: MicrO2 OSA Device with Micro-recorder
   Common Name: Intraoral appliance for snoring and obstructive sleep apnea
   510(k) Clearance Number: K161624

   Indications for Use: The MicroDental, Inc. MicrO2 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 into the MicrO2 device, the micro-recorder is intended to measure patient compliance to the oral appliance therapy in combination with the DentiTrac® System.

   Reference Device:
   Trade Name: SomnoDent Fusion with Micro Recorder
   Common Name: Intraoral appliance for snoring and obstructive sleep apnea
   510(k) Clearance Number: K150369

   Reference Device:
   Trade Name: Narval CC
   Common Name: Intraoral appliance for snoring and obstructive sleep apnea
   510(k) Clearance Number: K113201

Substantial equivalence is based on identical indications for use, technological characteristics and *in vitro* testing performed. The Risk Management file was updated to include the design modifications and no new risks were identified.

The device with embedded screws that are subject of this premarket notification and the predicate device have the same indications for use. Specifically, both the predicate MicrO2 OSA Device and the Prosommus [CA] Sleep and Snore Device that is subject of this Traditional 510(k) is indicated for

nighttime snoring and mild to moderate sleep apnea in adults. The option of the compliance chip is available in the same fashion as in the MicrO2 OSA Device. No changes are being made to the materials, technological characteristics or principles of operation as a result of this premarket notification. Both devices are inserted into the mouth and are adjusted or exchanged according to physician prescription. The differences between the subject device and the predicate device are as follows although these modifications are identical to the reference predicate as noted above. The reference predicate was successfully used as a predicate for the MicrO2 OSA Device with DentiTrac MicroRecorder:

- Embedded screw
- Patient locking key

The digital milling manufacturing process and material are the same. Data relied upon to determine substantial equivalence of the Prosomnus [CA] Sleep and Snore device with the device modifications described in this submission to the cleared MicrO2 OSA device include the following:

Test Description
Compression and Shear Torsion Testing
Package and Distribution Testing

There are no changes being made to the compliance chip placement or process as a result of this submission.

Conclusions can be drawn from the tests that the modifications to the Prosomnus [CA] Sleep and Snore Device are substantially equivalent and meet the performance specifications.