April 6, 2026

ProSomnus Sleep Technologies
Divya Mavalli
Vice President, Regulatory & Quality
5675 Gibraltar Drive
Pleasanton, California 94588

Re: K252765
Trade/Device Name: ProSomnus RPMO2 OSA Device (RPMO2 OSA)
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, LQZ, DQA, OUG
Dated: March 4, 2026
Received: March 5, 2026

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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)*
K252765

Device Name
ProSomnus RPMO2 OSA Device (RPMO2 OSA)

Indications for Use *(Describe)*
The ProSomnus® RPMO2 OSA Device is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Additionally, the fully embedded RPMO2 oximeter sensor measures, displays, stores, and transmits functional oxygen saturation of the arterial hemoglobin (SpO2) and pulse rate. It is intended for continuous data collection during sleep. It can be used in sleep labs, long-term care, hospitals and home use.

When used in combination with the ProSomnus Oxymetrx App and ProSomnus Oxymetrx Provider Portal, the device enables remote collection of patients' physiological data.

The device is intended to be applied in the oral cavity.

The device is intended for use under non-motion conditions in well-perfused areas.

The device is single patient, reusable.

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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR §807.92.

1. Submitter Information

Applicant: ProSomnus Sleep Technologies
Address: 5675 Gibraltar Drive, Pleasanton, CA 94588
Contact Person: Divya Mavalli, VP of Regulatory & Quality
Telephone: 925-307-7069
Email: dmavalli@prosomnus.com
Date Prepared: March 4, 2026

2. Device Name

Trade Name: ProSomnus® RPMO_2 OSA Device
Common Name: Intraoral device for snoring and/or obstructive sleep apnea with patient monitoring
Classification Name: Intraoral devices for snoring and/or obstructive sleep apnea
Regulation Number: 21 CFR 872.5570, 21 CFR 870.2700, 21 CFR 880.6310
Product Codes: LRK, LQZ, PLC, DQA, OUG

3. Predicate and Reference Devices

Predicate Device: ProSomnus® EVO Sleep and Snore Device with Patient Monitoring (K202529)
Reference Device: Oxiband (Checkme™) O2 Pulse Oximeter (K191088)

4. Device Description

The ProSomnus® RPMO_2 OSA Device is a prescription, patient-specific, intraoral mandibular advancement device designed to treat snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The device consists of custom-fitted maxillary and mandibular arches that reposition the mandible to maintain upper airway patency during sleep.

The device incorporates a fully embedded, proprietary reflective pulse oximetry sensor within the maxillary arch. The embedded sensor noninvasively measures functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate during sleep. The device is powered by a rechargeable lithium-ion polymer battery and is provided non-sterile.

Physiological data collected by the device are stored and transmitted wirelessly to the ProSomnus® Oxymetrx™ App and the ProSomnus® Oxymetrx™ Provider Portal for non-real-time review by patients

and healthcare professionals. The device does not provide alarms or real-time physiological monitoring. The monitoring functionality is adjunctive and does not alter the device's intended therapeutic use or clinical decision-making in real time.

5. Indications for Use

The ProSomnus® RPMO_2 OSA Device is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Additionally, the fully embedded RPMO_2 oximeter sensor measures, displays, stores, and transmits functional oxygen saturation of the arterial hemoglobin (SpO_2) and pulse rate. It is intended for continuous data collection during sleep. It can be used in home settings, sleep laboratories, long-term care facilities, and hospitals.

When used in combination with the ProSomnus® Oxymetrx™ App and ProSomnus® Oxymetrx™ Provider Portal, the device enables remote collection of patients' physiological data.

The device is intended to be applied in the oral cavity.
The device is intended for use under non-motion conditions in well-perfused areas.
The device is single patient, reusable.

6. Technological Characteristics

The ProSomnus® RPMO_2 OSA device shares the same therapeutic mechanism, anatomical site, patient population, device materials, and intended use as the predicate ProSomnus® EVO Sleep and Snore Device.

Both devices utilize mandibular advancement to maintain upper airway patency during sleep. Both are custom-fabricated intraoral appliances intended for nightly use by adult patients.

Primary Technological Difference:

The primary technological difference between the subject and predicate devices is the monitoring technology. The predicate device incorporates a temperature-sensing micro-recorder intended to monitor patient wear-time compliance. The subject device incorporates an embedded reflective pulse oximetry sensor intended to continuously monitor SpO_2 and pulse rate during sleep. The wear-time for the subject device is assessed based on the presence of valid physiological signals.

The embedded oximeter is passive in nature and does not deliver therapy, provide alarms, or influence mandibular positioning. The addition of the embedded oximeter does not introduce new patient-contacting materials or alter the fit of the oral appliance.

7. Substantial Equivalence

The ProSomnus® $RPMO_2$ OSA Device and the ProSomnus® EVO Sleep and Snore Device have the same intended use and utilize the same therapeutic mechanism of action—mandibular advancement to maintain airway patency during sleep.

The differences in monitoring technology do not alter the therapeutic function of the device. The embedded $RPMO_2$ oximeter sensor serves as an adjunctive monitoring feature and does not affect mandibular advancement, airway patency, or patient comfort.

Non-clinical and clinical performance data demonstrate that the technological differences between the subject and predicate devices do not raise new questions of safety or effectiveness.

Table 1: Technical and Performance Comparison – Subject vs. Predicate Device

Parameter	ProSomnus® $RPMO_2$ OSA Device (Subject)	ProSomnus® EVO Sleep and Snore Device with Patient Monitoring (Predicate – K202529)	Substantial Equivalence or Differences
Manufacturer	ProSomnus Sleep Technologies	ProSomnus Sleep Technologies	Substantially equivalent.
Product codes	LRK, LQZ, PLC, DQA, OUG	LRK, LQZ, PLC	Substantially equivalent. The subject device is substantially equivalent to the predicate device with respect to the shared product codes (LRK, LQZ, PLC). The subject device additionally incorporates an oximetry function associated with product code DQA, and a software component, including the ProSomnus® Oxymetrx™ App and Provider Portal, associated with product code OUG. These additional product codes do not affect the safety or effectiveness of the subject device.
Classification	Class II (special controls)	Class II (special controls)	Substantially equivalent.
Regulation number	21 CFR 872.5570 - Intraoral devices for snoring and intraoral devices for snoring	21 CFR 872.5570 - Intraoral devices for snoring and intraoral devices for snoring	Substantially equivalent.

	and obstructive sleep apnea. 21 CFR 870.2700 - Oximeter. 21 CFR 880.6310 - Medical Device Data System.	and obstructive sleep apnea.	
Indications for Use	The ProSomnus® $RPMO_2$ OSA Device is intended to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in adults. Additionally, the fully embedded $RPMO_2$ oximeter sensor measures, displays, stores, and transmits functional oxygen saturation of the arterial hemoglobin (SpO_2) and pulse rate. It is intended for continuous data collection during sleep. It can be used in home settings, sleep laboratories, long-term care facilities, and hospitals. When used in combination with the ProSomnus® Oxymetrx™ App and ProSomnus® Oxymetrx™ Provider Portal, the device enables remote collection of patients' physiological data. The device is intended to be applied in the oral cavity. The device is intended for use under non-motion conditions in well-perfused areas. The device is single patient, reusable.	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.	Substantially equivalent, except for the replacement of the chec® micro-recorder with $RPMO_2$ oximeter sensor for adjunctive physiological monitoring.
Primary therapeutic function	Mandibular advancement for treatment of snoring and mild to moderate OSA	Mandibular advancement for treatment of snoring and mild to moderate OSA	Substantially equivalent.
Mode of operation	Mandibular Repositioning Device	Mandibular Repositioning Device	Substantially equivalent.

Mandibular advancement range	Advancements up to 12 mm may be achieved with additional arches as prescribed by the prescriber	Advancements up to 12 mm may be achieved with additional arches as prescribed by the prescriber	Substantially equivalent.
Patient population	Adults	Adults	Substantially equivalent.
Anatomical site of use	Oral cavity	Oral cavity	Substantially equivalent.
Device configuration	Custom maxillary and mandibular arches	Custom maxillary and mandibular arches	Substantially equivalent.
Materials in contact with patient	Medical-grade copolyester and adhesive	Medical-grade copolyester and adhesive	Substantially equivalent.
Splint design	Maximizes tongue space and mandibular movement resulting in the ability to open and close during wear	Maximizes tongue space and mandibular movement resulting in the ability to open and close during wear	Substantially equivalent.
Sensor placement	 Incorporates a fully embedded reflective pulse oximetry sensor within the maxillary arch of the intraoral appliance. The sensor is fully embedded within the device structure and positioned to maintain stable contact with the oral mucosa for continuous, physiological data collection during sleep.	 Incorporates a thermal compliance sensor positioned to detect intraoral temperature changes for the purpose of wear-time monitoring only. The predicate sensor does not measure SpO_2 or pulse rate and does not require optical signal acquisition.	Different. The subject device embeds a reflective pulse oximetry sensor within the maxillary arch to enable adjunctive physiological monitoring, whereas the predicate device positions a temperature sensor within the mandibular arch for wear-time detection only. This difference does not affect therapeutic function, safety, or effectiveness.
Post design	Upper guided posterior blocks and guided lower posts	Upper and lower radius posts	Different. Mechanical test evidence demonstrates loads tolerance remains acceptable for intended use.
Monitoring technology	Embedded reflective pulse oximetry sensor	Temperature compliance micro-recorder/sensor	Different.

			Different sensing modality; therapeutic function unaffected.
Measured parameters	SpO_2 and pulse rate	Temperature	Different. The measured parameters are different, but both are adjunctive non-therapeutic.
Measurement principle	Optical reflectance photoplethysmography	Thermal detection of intraoral temperature	Different. Different measurement principles are used for adjunctive monitoring only (optical reflectance PPG vs thermal detection). Both systems are passive, non-therapeutic, and do not influence mandibular advancement or clinical decision-making; therefore, this difference does not affect safety or effectiveness.
Data collection mode	Continuous during sleep	Continuous during sleep	Substantially equivalent.
Physiological SpO_2 accuracy specification	SpO_2 (70–100%): Below 70% no definition ±3.5% Pulse rate: ±3 bpm or ±3% (whichever is greater)	Not applicable** (no SpO_2 measurements)	Different when compared to predicate, but similar to the reference device. Clinical/bench validation results in submission.
SpO_2 resolution	1%	Not present	Different when compared to predicate, but similar to the reference device. The predicate device does not measure SpO_2.
Pulse rate specification range	45 – 220 bpm	Not present (no pulse rate measurements)	Different when compared to predicate, but similar to the reference device. Clinical/bench validation results in submission.
Pulse rate resolution	1 bpm	Not applicable	Different when compared to predicate, but similar to the reference device. The predicate device does not measure pulse rate parameters.

Battery life	4+ hours of continuous recording per session	4+ hours of continuous recording per session	Substantially equivalent. Both devices meet the daily recording time requirement.
Power supply	Internal electric powered	Internal electric powered	Substantially equivalent.
Degree of protection against electric shock	Type BF applied parts	DentiTrac® does not have a published IEC degree of protection against electric shock rating.	Different. The $RPMO_2$ sensor is classified as a Type BF applied part under IEC 60601-1, whereas the DentiTrac® sensor does not publish a formal applied part classification. Both devices are battery-powered, fully encapsulated intraoral sensors with no mains connection and no accessible live components. This difference in formal classification does not affect electrical safety, intended use, or performance and does not raise new questions of safety or effectiveness.
Data storage capacity	Up to 24 hours	Up to six months of wear-time data	Different. Differences in data storage reflect monitoring system design and do not impact therapeutic function or clinical performance.
Data transmission	Wireless transfer to mobile app and cloud-based provider portal	Infrared transfer via base station to web-based portal	Different. The subject device utilizes Bluetooth Low Energy for direct transfer to a mobile application and Wi-Fi/cellular network transfer to cloud platform, while the predicate device uses infrared communication to transfer to the base station, which then transfers to a web-based portal. Wireless functionality was evaluated for EMC, RF compliance, and cybersecurity per applicable

			standards and FDA guidance. Data transmission does not affect therapeutic delivery; therefore, this difference does not affect safety or effectiveness.
Alarms	None	None	Substantially equivalent.
Power source	Rechargeable Li-ion polymer battery	Non-rechargeable Li-ion coin cell battery	Different. The rechargeable power source supports monitoring functionality only. Both are fully embedded and were evaluated for electrical, thermal, and battery safety. Battery type does not affect therapeutic function; therefore, this difference does not impact safety or effectiveness.
Sterility	Non-sterile	Non-sterile	Substantially equivalent.
Waterproof grade	IP68 for Device IP22 for Charging Station	Fully embedded, but not rated	Substantially equivalent. Embedding process and device materials used are the same.
Wireless	Bluetooth Low Energy (BLE)	Infrared	Different. Both are wireless, but subject device uses BLE communication and predicate device uses infrared communication. BLE RF communication was evaluated for EMC, RF compliance, and cybersecurity; wireless functionality does not affect therapeutic delivery and therefore does not impact safety or effectiveness.
Sensor communication effective range	Within 10 meters	Within 0.2 meter	Different. The predicate device sensor communication range is smaller. The safety testing for radiofrequency is submitted. This difference

			does not affect the safety or effectiveness of mandibular advancement therapy.
Storage and transportation conditions	The oral appliance material itself should not be exposed to extreme temperatures in excess of 60°C (140°F). -25°- 55°C (-13°- 131°F) Relative humidity ≤85% (in a non-controlled environment and does not apply to oral wear). No corrosive gas. Good ventilation. Air pressure not less than 740mbar indoor storage and transportation.	The oral appliance material itself should not be exposed to extreme temperatures in excess of 60°C (140°F). While the embedded DentiTrac® sensor has a wider tested temperature range for operation (33°C to 39.2°C for wear, and a potential -25°C to 60°C for general environmental tolerance.	Substantially equivalent.
Operating condition	5°- 40°C (41°- 104°F) Do not operate when pressure is below 740 mbar.	Ambient indoor conditions typical for home use during sleep	Substantially equivalent. Differences are attributable to inclusion of electronic components and do not affect clinical performance.
Atmospheric pressure	>= 740 mbar	Not applicable	Different. Atmospheric pressure limitations for the subject device do not impact therapeutic function.
Body material	Same	Same	Substantially equivalent.
Contacting type	Oral mucosa	Oral mucosa	Substantially equivalent.
Contact duration	Less than 24 hours	Less than 24 hours	Substantially equivalent.
Prescription use	Yes	Yes	Substantially equivalent.
Shear strength - side-to-side (acceptance criteria)	≥ 30 lbf (pass)	≥ 30 lbf (pass)	Substantially equivalent.
Shear strength - front-to-back (acceptance criteria)	≥ 75 lbf (pass)	≥ 75 lbf (pass)	Substantially equivalent.
Standards utilized	AAMI TIR57 ANSI C62.4 ASTM D4169-16 EN 50663:2017 EN 62479:2010 EN IEC 62368 EN IEC 62368-1	ISO 7405 ISO 10993-1 ISO 10993-2 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-12 ASTM D4169-16	Different. Additional standards applied to the subject device address electronic, software, wireless, and monitoring features not present in the predicate

	FCC Title 47, Part 15, Subpart B IEC 60529 IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 62133-2 IEC 62304 IEC 62321-1-1 IEC 62321-1-4 IEC 62321-1-5 IEC 62321-1-6 IEC 62321-1-7-1 IEC 62321-1-7-2 IEC 62321-1-8 IEC 62321-3-1 IEC 62471 IEC/EN 62133-2 ISO 15223-1 ISO 80601-2-61 ISO/TR 24971 UN 38.3		device and do not affect the safety or effectiveness of the therapeutic function.
Biocompatibility	The device uses the same patient-contacting materials as the predicate and contacts the same intraoral tissues, with a comparable cumulative exposure profile; therefore, predicate biocompatibility testing is leveraged.	ISO 7405 ISO 10993-5 ISO 10993-10 ISO 10993-11 ISO 10993-12	Substantially equivalent.
Federal Communications Commission (FCC)	Complies with part 15 and 18 of FCC Rules	Not applicable.	Different. DentiTrac® micro-recorder uses infrared communication and does not transmit radio frequencies, so no FCC certification for wireless devices required. The subject device complies to FCC Rules.
Usability	Single patient, multiple use	Single patient, multiple use	Substantially equivalent.
Clean	Daily	Daily	Substantially equivalent.

The technological differences identified between the ProSomnus® $RPMO_2$ OSA Device and the predicate device are limited to adjunctive monitoring features, power source, data transmission methods, and design modifications required to integrate the embedded $RPMO_2$ oximeter sensor. These differences do not alter the therapeutic mechanism of action, intended use, anatomical site of use, patient-contacting materials, or clinical performance of mandibular advancement therapy, and therefore do not affect the safety or effectiveness of the subject device.

8. Performance Data

a. Non-Clinical Performance Testing

A comprehensive verification and validation program was conducted to evaluate mechanical integrity, electrical safety, battery performance, wireless data transmission reliability, ingress protection (IP68), software functionality, cybersecurity controls, and biocompatibility of patient-contacting materials.

Comparative mechanical testing, including front-to-back and side-to-side shear strength testing, demonstrated that the $RPMO_2$ OSA Device meets predefined acceptance criteria representative of clinically relevant loading conditions and retains sufficient mechanical strength for its intended use.

b. Clinical Performance Data

A clinical performance study was conducted to evaluate the accuracy and reliability of the embedded $RPMO_2$ reflective pulse oximeter under conditions representative of intended use.

The study assessed functional oxygen saturation (SpO_2) measurement accuracy across the range of 70–100% by comparison to arterial oxygen saturation determined by CO-oximetry. Pulse rate measurements were evaluated by comparison to electrocardiography (ECG). The study design and performance endpoints were consistent with FDA guidance and recognized standards applicable to pulse oximetry devices.

Clinical results demonstrated that the $RPMO_2$ oximeter met predefined acceptance criteria for SpO_2 and pulse rate accuracy across clinically relevant ranges. The device performed consistently throughout the study, and no device-related adverse events were reported. The clinical data support that the embedded $RPMO_2$ oximeter performs as intended when integrated into the intraoral mandibular advancement device and does not adversely affect the safety, mechanical integrity, or therapeutic effectiveness of the oral appliance.

c. Software & Firmware

The ProSomnus® $RPMO_2$ OSA Device incorporates embedded firmware and associated software to support physiological data acquisition, processing, storage, and communication. The firmware

controls the operation of the integrated $RPMO_2$ oximeter sensor, including sensor activation, signal conditioning, data sampling, and preliminary signal processing to derive oxygen saturation (SpO_2) and pulse rate measurements. The firmware also manages device status monitoring, error detection, and data integrity checks to ensure reliable operation during patient use.

The system software includes a patient-facing mobile application and a provider-facing web portal. The mobile application supports device management, data upload, data display, and patient interaction. The provider portal supports clinician review and visualization of recorded data. Software functions include secure data communication, data storage, and presentation of measured parameters in a manner consistent with the device's intended use as a monitoring system. Clinical interpretation of data is performed through the provider portal and is not intended to occur within the mobile application. Software functions include secure data communication, data storage, and presentation of measured parameters in a manner consistent with the device's intended use. The software does not provide autonomous diagnostic or treatment decisions; rather, it supports the recording and review of physiological data in conjunction with prescribed therapy.

Software and firmware were developed under a controlled design process in accordance with the Quality System Regulation and applicable software lifecycle standards. A Moderate level of concern was assigned, and software documentation was prepared consistent with *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices—Guidance for Industry and FDA Staff,"* for Moderate level of concern devices. Verification and validation activities were performed to confirm that software and firmware requirements were correctly implemented and that the system performs as intended under normal and foreseeable conditions of use. Configuration management, change control, and anomaly resolution processes are in place to maintain software integrity throughout the product lifecycle.

d. Cybersecurity

The device complies with FDA guidance *"Cybersecurity in Medical Devices—Quality System Considerations and Content of Premarket Submissions"* (June 2025). Cybersecurity has been incorporated throughout the device lifecycle in accordance with Quality System requirements, including risk management, secure design controls, and verification and validation activities.

A cybersecurity risk assessment was conducted to identify potential threats and vulnerabilities associated with the device and its software. Appropriate controls were implemented to mitigate identified risks, including access controls, data protection measures, secure communication mechanisms, and safeguards to ensure the confidentiality, integrity, and availability of data. Cybersecurity controls were verified and validated to demonstrate their effectiveness under normal and foreseeable conditions of use.

The premarket submission includes documentation describing the device's cybersecurity architecture, risk management activities, and testing results, consistent with FDA expectations for devices with software and connectivity features.

Cybersecurity risk management continues following market release through post-market activities, including monitoring for newly identified vulnerabilities, review of publicly disclosed cybersecurity issues relevant to system components, and deployment of security patches or other mitigations when appropriate.

e. Analysis of Safety and Effectiveness

The ProSomnus® $RPMO_2$ OSA Device and the ProSomnus® EVO Sleep and Snore Device share the same therapeutic mechanism of action: mandibular advancement to maintain airway patency during sleep. The embedded $RPMO_2$ oximeter does not provide therapy, does not influence mandibular positioning, and does not interact with the mechanical advancement features of the device.

Although absolute shear strength values for the $RPMO_2$ device are lower than those of the FDA-cleared predicate device, acceptance criteria are met with significant margins. The observed differences are attributable to design differences associated with integration of the embedded $RPMO_2$ oximeter sensor and do not compromise clinical performance, durability, or safety.

From a safety perspective:

- The embedded oximeter is fully enclosed within the oral appliance.
- No new patient-contacting materials are introduced.
- Structural integrity and resistance to clinically relevant forces are preserved.

From an effectiveness perspective:

- Mandibular advancement capability and retention are unchanged.
- Shear testing confirms that the device can withstand forces encountered during intended use.
- The additional monitoring functionality does not interfere with therapeutic performance.

In addition to comparative shear strength testing, the ProSomnus® $RPMO_2$ OSA Device was evaluated through a comprehensive verification and validation test program. Testing was conducted to confirm that integration of the embedded $RPMO_2$ oximeter sensor does not adversely affect device safety, mechanical integrity, electrical performance, or intended clinical function.

Testing included, as applicable, evaluations of:

- Electrical safety and battery performance
- Wireless data transmission reliability
- Environmental protection and ingress resistance (IP68)

- Biocompatibility of patient-contacting materials
- Software and cybersecurity controls supporting data transmission and storage
- Oximeter performance verification under expected intraoral conditions of use

All testing met predefined acceptance criteria and supports that the ProSomnus® $RPMO_2$ OSA Device performs as intended and maintains safety and effectiveness equivalent to the predicate device.

9. Conclusions

The ProSomnus® $RPMO_2$ OSA Device is substantially equivalent to the predicate ProSomnus® EVO Sleep and Snore Device based on comparable intended use, therapeutic mechanism, materials, and design characteristics.

Bench testing, electrical and software verification, and clinical performance data demonstrate that the addition of the embedded $RPMO_2$ oximeter sensor does not raise new questions of safety or effectiveness. The device performs as intended and maintains safety and effectiveness equivalent to the predicate device.

Therefore, the ProSomnus® $RPMO_2$ OSA Device meets the criteria for substantial equivalence under Section 513(i) of the Federal Food, Drug, and Cosmetic Act.