August 29, 2025

Sunrise SA
Grégoire Lejeune
Hardware Manager
Chaussée de Marche, 598/02
Namur, 5101
Belgium

Re: K250874
Trade/Device Name: Sunrise Air
Regulation Number: 21 CFR 868.2376
Regulation Name: Device For Sleep Apnea Testing Based On Mandibular Movement
Regulatory Class: Class II
Product Code: QRS
Dated: March 24, 2025
Received: August 1, 2025

Dear Grégoire Lejeune:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250874

Device Name
Sunrise Air

Indications for Use *(Describe)*
The Sunrise Air is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders.

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

1. SUBMITTER

Sunrise SA
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Belgium

Phone: +32 81 26 11 26

Contact Person: Grégoire Lejeune
Date Prepared: August 29, 2025

2. DEVICE

Name of Device: Sunrise Air
Common or Usual Name: Sleep apnea testing
Classification Name: Device for sleep apnea testing based on mandibular movement
Regulatory Class: II
Product Code: QRS
Regulation: 21 CFR 868.2376
Classification Panel: Anesthesiology

3. PREDICATE DEVICE

Predicate Device: Sunrise (K222262)
Reference Device: SOMNOscreen plus (K201054)

4. DEVICE DESCRIPTION

The Sunrise Air consists of the Sunrise software (v1.28.00), which analyzes data from one of three compatible sensors (Sunrise sensor 1, Sunrise sensor 2, or Sunrise Air) placed on the patient's chin. Sunrise sensor 1 was approved through DEN210015, while Sunrise sensor 2 was cleared through K222262. The current version of the Sunrise device introduces a new sensor, Sunrise Air. The Sunrise device is intended to detect respiratory events, identify sleep stages and position, and generate key sleep parameters—such as the apnea-hypopnea index ("Sunrise AHI") and positional states classifications. The collected data is compiled into a report for further interpretation by a healthcare provider.

5. INDICATIONS FOR USE

The Sunrise Air is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sunrise software, cleared under 510(k) K222262, is now compatible with an additional accessory: the Sunrise Air. The Sunrise algorithm—a component of the Sunrise software—has been updated to process raw data acquired by the optical module in both the Sunrise sensor 2 and the Sunrise Air.

The Sunrise Air retains the same features as the Sunrise sensor 2, with the following enhancements:

- Addition of a microphone;
- Integration of a rechargeable battery.

Item	**Subject device** **Sunrise Air**	**Predicate device** **Sunrise (K222262)**	**Reference device** **SOMNOscreen plus (K201054)**	**Comparison**
Classification product code *Subsequent product code*	QRS	QRS	OLV *MNR*	Same as predicate device
Intended use/indications for use	The Sunrise Air is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders.	The Sunrise device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders.	The SOMNOscreen plus is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders. The device is a non-life-supporting physiological signal recording device intended to be used for studies testing adults and children/adolescents suspected of having sleep-related breathing disorders. This device is NOT	Same as predicate device

Item	Subject device Sunrise Air	Predicate device Sunrise (K222262)	Reference device SOMNOscreen plus (K201054)	Comparison
			designed to be used in a Life Support situation. This device is not designed for use on patients with cardiac pacemakers.	
Target population	18 years and older	18 years and older	2 years and older	Same as predicate device
Type of use	Prescription	Prescription	Prescription	Same as predicate device
Intended use environment	Clinical or home	Clinical or home	Clinical or home	Same as predicate device
Wearable location	Chin	Chin	Multiple locations	Same as predicate device
Hardware components	Accelerometer, gyroscope Optical module, thermistor (Sunrise sensor 2 and Sunrise Air) Microphone (Sunrise Air)	Accelerometer, gyroscope Optical module, thermistor (Sunrise sensor 2)	Multiple components including microphone	Same as predicate device for accelerometer, gyroscope, optical module, and thermistor, same as reference device for microphone
Channels	Mandibular jaw movements, movement, position, respiratory effort Airflow, photoplethysmography, pulse rate, oxygen saturation (Sunrise sensor 2 and Sunrise Air) Snore (Sunrise Air)	Mandibular jaw movements, movement, position, respiratory effort Airflow, photoplethysmography, pulse rate, oxygen saturation (Sunrise sensor 2)	Multiple channels including snore	Same as predicate device for mandibular jaw movements, movement, position, respiratory effort, airflow, photoplethysmography, pulse rate, and oxygen saturation, same as reference device for snore
Size and weight	42x17x6mm - 3g (Sunrise sensor 1) 40x22x12mm - 8g (Sunrise sensor 2) 44x20x8mm - 15g (Sunrise Air)	42x17x6mm - 3g (Sunrise sensor 1) 40x22x12mm - 8g (Sunrise sensor 2)	Multiple sizes and weights	Same as predicate device (Sunrise sensor 1 and Sunrise sensor 2) Substantially equivalent to predicate device (Sunrise Air)
Raw data recording	Streamed to smartphone (Sunrise sensor 1) or on-board memory (Sunrise sensor 2 and Sunrise Air)	Streamed to smartphone (Sunrise sensor 1) or on-board memory (Sunrise sensor 2)	Streamed to computer or on-board memory	Same as predicate device
Power supply	Non-rechargeable lithium coin battery	Non-rechargeable lithium coin battery	Rechargeable lithium-ion battery	Same as predicate device (Sunrise

Item	Subject device Sunrise Air	Predicate device Sunrise (K222262)	Reference device SOMNOscreen plus (K201054)	Comparison
	(Sunrise sensor 1 and Sunrise sensor 2) or rechargeable lithium-ion battery with ~500 charging cycles (Sunrise Air)		with ~500 charging cycles	sensor 1 and Sunrise sensor 2) Same as reference device (Sunrise Air)
User interface	Smartphone and computer	Smartphone and computer	Computer	Same as predicate device
Patient contact type	In contact with intact skin surfaces for prolonged duration	In contact with intact skin surfaces for limited duration	In contact with intact skin surfaces for limited duration	Same contact type as predicate device, longer duration due to potential for repeated applications
Wearable software	Firmware is limited to control the recording and communications processes	Firmware is limited to control the recording and communications processes	Firmware is limited to control the recording and communications processes	Same as predicate device
Analysis software	Analysis performed off the recording device, exclusively cloud-based, by the proprietary software	Analysis performed off the recording device, exclusively cloud-based, by the proprietary software	Analysis performed off the recording by the proprietary software	Same as predicate device
Sterility	Non-sterile	Non-sterile	Non-sterile	Same as predicate device
Parameters	TST, wake and light/deep/REM sleep, SOL, WASO, SE, awakening index, ArI, REM sleep latency, AHI, ORDI, RDI, OAHI, CAHI, RERA index, RE, sleep time in supine and non-supine positions Oxygen saturation and pulse rate statistics (Sunrise sensor 2 and Sunrise Air) Snore statistics (Sunrise Air)	TST, wake and light/deep/REM sleep, SOL, WASO, SE, awakening index, ArI, REM sleep latency, AHI, ORDI, RDI, OAHI, CAHI, RERA index, RE, sleep time in supine and non-supine positions Oxygen saturation and pulse rate statistics (Sunrise sensor 2)	Multiple parameters including snore statistics	Same as predicate device, same as reference device for snore statistics
Pulse rate accuracy and measurement range	Accuracy (rms value) was found to be 2.73 beats per minute (bpm) for a claimed measurement range	Accuracy (rms value) was found to be 1.95 beats per minute (bpm) for a claimed measurement range	Claimed measurement range of 18 to 300 beats per minute (bpm)	Substantially equivalent to predicate device

Item	Subject device Sunrise Air	Predicate device Sunrise (K222262)	Reference device SOMNOscreen plus (K201054)	Comparison
	of 51 to 104 bpm (Sunrise sensor 2 and Sunrise Air)	of 51 to 104 bpm (Sunrise sensor 2)		
Means of attachment	Adhesives	Adhesives	Multiple means	Same as predicate device

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

The device includes three patient-contacting components that come into contact with the skin on the patient's chin during the sleep study: the housing, the optical module window, and the double-sided adhesive. The device is intended for prolonged surface contact with intact skin. A biocompatibility evaluation was conducted in accordance with the FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process."*

Software and Cybersecurity

The device has a moderate level of concern software component. Software verification and validation testing were conducted as recommended by the FDA guidance document *Content of Premarket Submissions for Device Software Functions*. Additionally, documentation was provided in accordance with the FDA guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* to demonstrate that appropriate cybersecurity measures have been implemented and will be monitored and updated throughout the device's life cycle.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the device to demonstrate compliance with the following standards: IEC 60601-1 for basic safety, IEC 60601-1-2 for electromagnetic compatibility, and IEC 60601-1-11 for use in the home healthcare environment. Documentation was provided in accordance with the FDA guidance document *Electromagnetic Compatibility (EMC) of Medical Devices.*

Bench Testing

Bench testing was conducted to demonstrate technical equivalence between the subject device, the predicate device, and the reference device. The signals measured by the accelerometer and gyroscope of the subject and predicate devices were compared, and their performance was found to be equivalent. No modifications have been made to the Sunrise algorithm used to generate sleep parameters.

The signal measured by the thermistor of the subject device was compared to that of the oronasal thermal airflow sensor of the reference device, demonstrating equivalent performance in capturing breathing patterns. The signal measured by the microphone of the subject device was compared to that of the microphone of the reference device (Somno HD), with comparable performance observed. During both no-snoring and snoring situations, the sound patterns were visually similar between the two devices, with synchronized transitions from no-snoring to snoring phases and comparable noise variations when snoring was present.

While raw PPG data acquisition remains identical between the Sunrise Air and the previously cleared version of the Sunrise device, PPG data processing was moved from an embedded algorithm on the sensor to a cloud-based algorithm (Sunrise PPG algorithm) Therefore, a validation study of SpO_2 and pulse rate accuracy for the subject device was conducted using raw PPG data acquired during the clinical validation for the Sunrise sensor 2 (K222262) which has the same interface window, optical module, and application site. The SpO2 accuracy (rms value) was found to be 1.91% over the range of 70-100%. The pulse rate accuracy (rms value) was found to be 2.73 beats per minute (bpm) for a claimed measurement range of 51 to 104 bpm.

8. CONCLUSION

Based on the performance data, the Sunrise Air is as safe and effective as the predicate device and performs equivalently. Therefore, the Sunrise Air is substantially equivalent to the predicate device.