December 22, 2022

Sunrise SA
Gregoire Lejeune
R&D project manager
Chaussee de Marche 598/02
Namur, 5101
Belgium

Re: K222262
Trade/Device Name: Sunrise
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: November 14, 2022
Received: November 18, 2022

Dear Gregoire 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 (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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number
K222262

Device Name
Sunrise

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*
X 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

1. SUBMITTER

Sunrise SA
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Belgium

Phone: +32 81 26 11 26

Contact Person: Grégoire Lejeune
Date Prepared: December 22, 2022

2. DEVICE

Name of Device: Sunrise
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 Sleep Disorder Diagnostic Aid (DEN210015)
Reference Devices: NightOwl (K191031), SOMNOscreen plus (K201054)

4. DEVICE DESCRIPTION

The Sunrise device is a cloud-based software device that analyzes data from a sensor (Sunrise sensor 1 or Sunrise sensor 2) placed on the patient's chin. The device detects respiratory events, identifies sleep stages and position. The device generates sleep parameters, e.g. apnea hypopnea index "Sunrise AHI", and position discrete states. Data collected by the device is integrated in a report for further interpretation by the healthcare provider.

5. INDICATIONS FOR USE

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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Sunrise software, subject of the De Novo DEN210015 with the Sunrise sensor 1, is now compatible with the Sunrise sensor 2. The Sunrise algorithm, component of the Sunrise software, has been updated to provide new sleep parameters.

The Sunrise sensor 2 presents the same features as the Sunrise sensor 1, with the following improvements:

- Addition of a PPG sensor to provide SpO2 and pulse rate measurement;
- Addition of a thermistor to provide airflow measurement;
- Battery for up to three nights of recording (compared to one night for the Sunrise sensor 1);
- On-board memory to record raw data for transfer at the end of the night.

Item	**Subject device** **Sunrise**	**Predicate device** **Sunrise sleep disorder diagnostic aid (DEN210015)**	**Reference device 1** **NightOwl (K191031)**	**Reference device 2** **SOMNOscreen plus (K201054)**	**Comparison**
Intended use/indications for use	The Sunrise medical 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 Sunrise SDDA 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 NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting	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	Same as predicate device

Item	Subject device Sunrise	Predicate device Sunrise sleep disorder diagnostic aid (DEN210015)	Reference device 1 NightOwl (K191031)	Reference device 2 SOMNOscreen plus (K201054)	Comparison
			use under the direction of a Healthcare Professional (HCP).	children/adolescents suspected of having sleep-related breathing disorders. This device is NOT 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	22 years and older	2 years and older	Same as predicate device
Type of use	Prescription	Prescription	Prescription	Prescription	Same as predicate device
Intended use environment	Home	Home	Home	Clinical or home	Same as predicate device
Wearable sensor location	Chin	Chin	Fingertip	Multiple locations including chin and fingertip	Same as predicate device
Sensors	Accelerometer Gyroscope PPG (Sunrise sensor 2 only) Thermistor (Sunrise sensor 2 only)	Accelerometer Gyroscope	Accelerometer PPG	Multiple sensors including accelerometer, PPG and thermistor	Same as predicate device for accelerometer and gyroscope, same as reference device 1 for PPG and same as reference device 2 for thermistor
Channels	Mandibular movements Discrete position SpO2 (Sunrise sensor 2 only) Pulse rate (Sunrise sensor 2 only)	Mandibular movements Discrete position	PAT SpO2 Pulse rate	Multiple channels including discrete position, SpO2, pulse rate and airflow	Same as predicate device for mandibular movements and discrete position, same as reference device 1 for SpO2 and pulse rate and same

Item	Subject device Sunrise	Predicate device Sunrise sleep disorder diagnostic aid (DEN210015)	Reference device 1 NightOwl (K191031)	Reference device 2 SOMNOscreen plus (K201054)	Comparison
	Airflow (Sunrise sensor 2 only)				as reference device 2 for airflow
Size and weight	42x17x6mm - 3g (Sunrise sensor 1) 40x22x12mm - 8g (Sunrise sensor 2)	42x17x6mm - 3g	19x28x11mm - 6g	Multiple sensors of different sizes and weights	Same as predicate device (Sunrise sensor 1) Substantially equivalent to predicate device (Sunrise sensor 2)
Raw data recording	Streamed to smartphone (Sunrise sensor 1) or on-board memory (Sunrise sensor 2)	Streamed to smartphone	Streamed to smartphone or on-board memory	Streamed to computer or on-board memory	Same as predicate device (Sunrise sensor 1) Substantially equivalent to predicate device and same as reference device 1 (Sunrise sensor 2)
Power supply	Non-rechargeable lithium coin battery	Non-rechargeable lithium coin battery	Rechargeable lithium ion battery	Rechargeable lithium ion battery	Same as predicate device
User interface	Smartphone and computer	Smartphone and computer	Smartphone and computer	Computer	Same as predicate device
Patient contact type	In contact with intact skin surfaces for limited duration	In contact with intact skin surfaces for limited duration	In contact with intact skin surfaces for limited duration	In contact with intact skin surfaces for limited duration	Same as predicate device
Wearable sensor 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	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	Analysis performed off the recording device, exclusively cloud-based, by	Analysis performed off the recording device, exclusively cloud-based, by	Analysis performed off the recording by the proprietary software	Same as predicate device

Item	Subject device Sunrise	Predicate device Sunrise sleep disorder diagnostic aid (DEN210015)	Reference device 1 NightOwl (K191031)	Reference device 2 SOMNOscreen plus (K201054)	Comparison
	the proprietary software	the proprietary software	the proprietary software		
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same as predicate device
Reported parameters	TST, SOL, WASO, SE, awakening index, ArI, light/deep/REM sleep, REM sleep latency, AHI, AHI supine, AHI non supine, AHI REM, AHI NREM, ORDI, ORDI supine, ORDI non supine, ORDI REM, ORDI NREM, RDI, OAHI, CAHI, AHI (4%), RERA index, RE, sleep time in supine position and sleep time in non supine position SpO2 and pulse rate statistics (Sunrise sensor 2 only)	TST, SOL, WASO, SE, ArI, ORDI, sleep time in supine position and sleep time in non supine position	TST, REM sleep, AHI, AHI (4%), SpO2 and pulse rate statistics	TST, SOL, WASO, SE, awakening index, ArI, light/deep/REM sleep, REM sleep latency, AHI, AHI supine, AHI non supine, AHI REM, AHI NREM, ORDI, ORDI supine, ORDI non supine, ORDI REM, ORDI NREM, RDI, OAHI, CAHI, AHI (4%), RERA index, RE, sleep time in supine position, sleep time in non supine position, SpO2 and pulse rate statistics	Same as predicate device for TST, SOL, WASO, SE, ArI, ORDI, sleep time in supine position and sleep time in non supine position, same as reference device 1 for TST, REM sleep, AHI, AHI (4%), SpO2 and pulse rate statistics, and same as reference device 2 for TST, SOL, WASO, SE, awakening index, ArI, light/deep/REM sleep, REM sleep latency, AHI, AHI supine, AHI non supine, AHI REM, AHI NREM, ORDI, ORDI supine, ORDI non supine, ORDI REM, ORDI NREM, RDI, OAHI, CAHI, AHI (4%), RERA index, RE, sleep time in supine position, sleep time in

Item	Subject device Sunrise	Predicate device Sunrise sleep disorder diagnostic aid (DEN210015)	Reference device 1 NightOwl (K191031)	Reference device 2 SOMNOscreen plus (K201054)	Comparison
					non supine position, SpO2 and pulse rate statistics
Pulse rate accuracy and measurement range	Accuracy (rms value) was found to be 1.95 beats per minute (bpm) for a claimed measurement range of 51 to 104 bpm (Sunrise sensor 2 only)	Not applicable	Accuracy (rms) value was found to be 2.26 beats per minute (bpm) for a claimed measurement range of 50 to 118 bpm	Claimed measurement range of 18 to 300 beats per minute (bpm)	Substantially equivalent to reference device 1
Means of attachment	Adhesives	Adhesives	Adhesives	Multiple means including adhesives	Same as predicate device

7. PERFORMANCE DATA

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

Biocompatibility

The device includes four patient-contacting components which are in contact with the skin of the chin of the patient during the sleep study: housing, PPG window, double-sided adhesive and additional adhesive bandage. Biocompatibility evaluation was conducted, and documentation was provided as recommended by 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

The device has a moderate level of concern software component. Software verification and validation testing were conducted, and documentation was provided as recommended by the FDA guidance document *Guidance for the Content of Premarket Submissions for Software contained in Medical Devices*.

Documentation was provided in accordance with the FDA guidance document *Content of Premarket Submissions for Management of Cybersecurity in Medical Device* to support adequate cybersecurity measures have been taken and will be monitored and updated throughout the device life cycle.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing were conducted on the device to demonstrate compliance with IEC 60601-1 standard for safety, IEC 60601-1-2 standard for EMC and IEC 60601-1-11 standard for home healthcare environment.

Bench Testing
Bench testing was conducted to demonstrate technical equivalency between the subject device and the predicate device. The measured signals of the accelerometer and of the gyroscope between the two sensors were compared and performance found to be equivalent.

Clinical Studies
The primary objective of the first three clinical studies was to compare the agreement of sleep parameters between the device and the gold-standard PSG. The algorithm was used to analyze sensor data and evaluate the performance of the device compared to PSG. The performance of the device for sleep parameters was evaluated by Bland-Altman analysis and percentiles-based limits of agreement (LOA) against pre-determined thresholds of clinical acceptability. The performance of the device for OSA severity output was evaluated as standard diagnostic metrics compared to the PSG at three different AHI cut-offs.

The first clinical study was a retrospective, comparative and open study performed in Belgium in 289 patients. Median measurement bias and LOA were -4.50 min (-41.74 to +35.67), -0.46 event/h (-13.52 to +9.00) and +0.15 event/h (-10.70 to +10.12) for TST, AHI and ORDI, respectively. Performance for OSA severity was as following: sensitivity of 0.99, 0.92, 0.81 and specificity of 0.86, 0.94 and 0.99 for AHI>=5, AHI>=15 and AHI>=30, respectively.

The second clinical study was a retrospective, comparative and open study performed in France in 31 patients. Median measurement bias and LOA were -10.50 min (-37.42 to +25.79), +0.20 event/h (-12.30 to +6.30) and +1.01 event/h (-11.24 to +6.21) for TST, AHI and ORDI, respectively. Performance for OSA severity was as following: sensitivity of 1.00, 0.94, 0.87 and specificity of 0.75, 1.00 and 1.00 for AHI>=5, AHI>=15 and AHI>=30, respectively.

The third clinical study was a retrospective, comparative and open study performed in Belgium in 10 patients. The performance of the device for position discrete states was evaluated as global accuracy compared to the PSG: 93%.

For the fourth clinical study, SpO2 and pulse rate accuracies for the Sunrise sensor 2 were validated in accordance with ISO 80601-2-61:2019 201.12.1.101.2 and Annex EE.2 as recommended by the FDA guidance document *Pulse Oximeters - Premarket Notification Submissions [510(k)s]*. The SpO2 accuracy (rms value) was found to be 2.70% over the range of 70-100%. The pulse rate accuracy (rms value) was found to be 1.95 beats per minute (bpm) for a claimed measurement range of 51 to 104 bpm.

In addition, a validation study was conducted to demonstrate the ability of the Sunrise

sensor 2 thermistor to capture airflow. The signal measured by the Sunrise sensor 2 thermistor was compared to that of an oronasal thermal airflow sensor used in PSG and the performance was found to be equivalent for capturing breathing patterns.

8. CONCLUSION

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