De Novo Classification Request for Sunrise Sleep Disorders Diagnostic Aid

Regulatory Information

FDA identifies this generic type of device as:

> **Device for sleep apnea testing based on mandibular movement.** A device for sleep apnea testing based on mandibular movement is a prescription device intended to aid in evaluation of sleep apnea during sleep in patients suspected of having sleep breathing disorders by analyzing sensor readings of mandibular movement. The device is not intended as a substitute for full polysomnography nor intended to be used as an apnea monitor.

New Regulation Number: 21 CFR 868.2376

Classification: Class II

Product Code: QRS

Background

Device Name: Sunrise Sleep Disorder Diagnostic Aid (SDDA)

Submission Number: DEN210015

Date De Novo Received: April 2, 2021

Sponsor Information:

Sunrise SA
Chaussée de Marche 598/02
5101 Namur BELGIUM

Indications for Use

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.

Limitations

The sale, distribution, and use of the Sunrise SDDA are restricted to prescription use in accordance with 21 CFR 801.109.

Sunrise sensor is only to be placed on the chin. If the sensor is not placed on the chin, it will affect the accuracy of test results.

Patients suffering from conditions affecting the rotation of the condyle in the temporo-mandibular joint cannot use the Sunrise SDDA since it is not compatible with detection of mandibular movements.

The device is not intended as a substitute for full polysomnography (PSG) nor intended to be used as an apnea monitor.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Sunrise SDDA device consists of a Sunrise sensor and a cloud-based software device that analyzes data from the sensor when placed on the patient's mandible. The device also includes a mobile application to record patient's responses to questions about their sleep quality and transfer sensor data to the cloud. By analyzing patient's mandibular movements, the device also detects obstructive respiratory disturbances, identifies sleep states, notifies about the Obstructive Sleep Apnea (OSA) severity in a categorical format (non-OSA, mild-OSA, moderate-OSA, severe-OSA), generates sleep structure information (namely, total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, arousal index) and head position discrete states. Data collected by the device is integrated in a report for further interpretation and diagnosis by the healthcare provider.

Figure 1 Sunrise Sensor Placed on Mandible

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY / MATERIALS

The Sunrise SDDA sensor includes two patient-contacting components which are in contact with the skin of the chin of the patient during the test overnight: skin adhesive (3M SC Spunlace Extended Wear Nonwoven Tape) and film dressing (3M Tegaderm film 16004) which are classified as skin-surface-devices with ≤ 30 days contact duration ('prolonged exposure'). Biocompatibility evaluation has been completed according to FDA Guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*

(https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf). The test articles were found non-cytotoxic per ISO 10993-5. The test articles were found to be non-sensitizing in tests for skin sensitization per ISO 10993-10. The test articles were found to be non-irritating in tests for irritation per ISO 10993-10.

All other components of the device system are not direct patient-contacting.

PACKAGING AND SHELF LIFE

Testing was conducted to evaluate the packaging and labeling of the Sunrise SDDA sensor to withstand anticipated shipping conditions while preserving the functionality of the device. This testing included freefall drop testing from (b)(4) resistance to rain and humidity, and label integrity evaluations. Each of these tests demonstrated that the packaging provides appropriate protection for the Sunrise SDDA sensor device, ensuring it will remain functional with legible labeling following distribution.

The Sunrise SDDA sensor is a non-sterile and single-use device intended to be placed on the chin. The shelf-life of the device is 2 years. This shelf-life was determined based on the shelf-life of the skin adhesive and specific storage conditions defined by the supplier.

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The following Electrical/Mechanical/Thermal Safety and Electromagnetic Compatibility (EMC) testing has been performed and results support electrical safety and electromagnetic compatibility:

- IEC 60601-1:2005+ CORR. 1:2006 + CORR. 2:2007 + A1:2012, General requirements for basic safety and essential performance for medical electrical equipment

- IEC 60601-1-2:2014, Medical electrical equipment Part 1-2 – General requirements for basic safety and essential performance – Electromagnetic compatibility.

SOFTWARE

The Sunrise SDDA device has a Moderate Level of Concern (LOC) software component. Appropriate documentation was provided to support the validation of the software for a Moderate LOC in accordance with FDA's 2005 guidance titled, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The sponsor also provided details on how the Machine Learning algorithms detect sleep disordered breathing events to estimate output parameters. The sponsor also demonstrated an overview of algorithm workflow, software handling of hardware error or failures and a summary of algorithms development and training steps.

Appropriate documentation was provided in accordance with FDA's 2014 guidance document titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" to support adequate cybersecurity measures have been taken and will be monitored and updated throughout the device life cycle.

PERFORMANCE TESTING - BENCH

The majority of performance testing for the Sunrise SDDA device are encapsulated in software section above and through validation of the overall system in clinical studies. Additionally, the sponsor performed bench testing to demonstrate equivalent technical performance between the Sunrise sensor and a head position sensor that was used in two retrospective clinical validation studies. Both head position and Sunrise sensors use the exact same inertial measurement unit and therefore, technical specifications including resolution, sensitivity, output data rate of accelerometer and gyroscope sensors are the same. To demonstrate dynamic performance equivalency between two sensors, a bench set up was prepared using a dummy head and a rotation disk. Sunrise and head position sensors were attached to the dummy head and movement data were recorded at different disk rotation speeds and directions from the chin area. The measured signals of the accelerometer and of the gyroscope between the two sensors were compared and dynamic performance found to be equivalent. Therefore, the retrospective clinical data collected with the head position sensor can used for performance evaluation of the Sunrise SDDA device.

HUMAN FACTORS/USABILITY

A Formative usability engineering testing in accordance with IEC 62366-1: 2015, "Medical devices — Part 1: Application of usability engineering to medical devices" was conducted in Belgium using (b)(4) adult users, (b)(of which were tech savvy, and (b) who were not considered to be tech savvy. The report describes the risk-based approach to assessment of use related risks. Based on the assessment, three risks were identified related to use of the Sunrise SDDA device: false negative, choking, and no result. Each user was required to complete (b) distinct tasks for use of the device using the provided Instructions for Use. The majority of participants in both user groups completed all tasks correctly, providing strong evidence for the appropriate design of the use interface and proposed labeling for the Sunrise SDDA device. None of these tasks were considered critical tasks, because Sunrise SDDA device is a prescription use device for aid in diagnosis of OSA and even a false negative result may delay the final diagnosis by few weeks and is not associated with a user task which if performed incorrectly or not performed could result in serious harm or serious compromise in medical care. The sponsor also stated that Sunrise SDDA device has previously been placed on the European market and no issues have been reported. The outcome of the usability study was assessed as satisfactory, because the testing provided adequate assurance that all tasks linked to a safety mitigation could be successfully performed by more than (b)(4)% of participants.

SUMMARY OF CLINICAL INFORMATION

The sponsor provided three clinical study protocols and reports to support the safety and effectiveness of the Sunrise SDDA device. The primary objective of all clinical studies was to compare the agreement of sleep parameters between Sunrise SDDA device and the gold-standard polysomnography (PSG). No adverse event, adverse device effects or device deficiencies were reported in conducted clinical studies. Patient recruitment of these studies was set up to ensure collection on a wide range of ages (18 years and older), sleep disordered breathing problems, body mass indices, and neck circumferences comparable to the US intended patient population.

The first clinical study was a retrospective, comparative and open study performed in Belgium in (b)(4) patients. The mandibular movement signals were recorded using a head position sensor and its equivalency to the Sunrise sensor was demonstrated using bench testing. The Sunrise Machine Learning algorithms were used to analyze sensor data and evaluate the performance of the device only for sleep structure parameters compared to in-lab PSG (i.e., Somnoscreen, Somnomedics). The PSG data were visually scored by an experienced sleep technician that was blind to the study protocol and hypothesis according to the 2012 American Academy of Sleep Medicine (AASM) recommendations. The performance of the device for sleep structure parameters was calculated as the root mean square error (RMSE) in a statistical non-inferiority test across all measurements when compared to the PSG. (b)(4) confidence intervals (CIs) were calculated for these measurements using the bootstrap method. The RMSEs were found to be (b)(4) (CI (b)(4) – (b)(4)), (b)(4) (CI (b)(4)), (b)(4) (CI (b)(4) – (b)(4)) and (b)(4) events/h (CI (b)(4) - (b)(4) events/h) for TST, SOL, WASO, SE and ArI, respectively. This clinical study, on its own, was not sufficient to demonstrate a reasonable assurance of safety and effectiveness use of the Sunrise SDDA device as the same datasets were used for both optimizing diagnostic thresholds (training) and performance evaluation (validation) of OSA severity.

The second study was a prospective, comparative and open clinical study independent from the first one and performed in France in (b)(4) patients. The final Sunrise sensor was used to record mandibular movements from patients. The clinical report focused on evaluating the performance of the device in terms of all output parameters (i.e., OSA severity and sleep structure measurements) compared to data recorded by an ambulatory at-home PSG system (i.e., NOX A1, ResMed). The PSG data were visually scored by experienced sleep technicians from two different sleep centers (Université Grenoble Alpes, Grenoble, France and Imperial College London, London, United Kingdom) according to the 2012 AASM recommendations. The performance of the device for OSA severity output was calculated as standard diagnostic metrics compared to the PSG at three different ORDI cut offs as following: sensitivity of (b)(4) and specificity of (b)(4) and (b)(4) for ORDI>(b)(4) ORDI>=(b)(4) and ORDI>=(b)(4) respectively. For sleep structure parameters, the RMSEs were found to be (b)(4) (CI (b)(4) – (b)(4)), (b)(4) (CI (b)(4) – (b)(4)), (b)(4) (CI (b)(4) - (b)(4)), (b)(4)% (CI (b)(4) – (b)(4) and (b)(4) events/h (CI (b)(4) - (b)(4) events/h) for TST, SOL, WASO, SE and ArI, respectively.

The third study was an independent clinical study with similar design as the first one, and was a retrospective, comparative and open study performed in Belgium in (b)(4) patients. The head position sensor was used to collect mandibular movement signals and the Sunrise SDDA algorithms analyzed sensor data and evaluated the performance of the device compared to in-lab PSG (Somnoscreen, Somnomedics). The PSG data were visually scored by an experienced sleep

technician that was blinded to the study protocol and hypothesis according to the 2012 AASM recommendations. The performance of the device for OSA severity output was calculated similarly to the second study as follows: sensitivity of (b)(4) and specificity of (b)(4) and (b)(4) for ORDI>=(b)(ORDI>=(b)(and ORDI>=(b)(4 respectively. For sleep structure parameters, the RMSEs were found to be (b)(4) (CI (b)(4) – (b)(4)), (b)(4) (CI (b)(4) – (b)(4)), (b)(4) (CI (b)(4) – (b)(4) , (b)(4) (CI (b)(4) – (b)(4) and (b)(4) events/h (CI (b)(4) – (b)(4) events/h) for TST, SOL, WASO, SE and ArI, respectively.

Pediatric Extrapolation

The Sunrise SDDA device is indicated for patients aged 18 and older. For medical devices, the FD&C Act defines patients before their 22nd birthday as pediatric patients. In this De Novo request, data from patients between 18-22 were used to support the use of the device in patients over the age of 18. It was appropriate to indicate the device for individuals 18 and older because of this data and patients aged 18 to 21 do not carry additional differences or risks relative to the patient population studied.

LABELING

The labeling meets the requirements of 21 CFR 801.109 for prescription devices and includes a description of what the device measures and outputs to the user. A summary of the clinical validation data provides expected performance for intended use populations and environments. As certain conditions affecting the rotation of the condyle in the temporo-mandibular joint may confound accurate readings, patients suffering from such conditions should not use this device. Other patient conditions that may affect performance of the device are listed in the labeling. The labeling provides instructions on the system set-up, taking measurements, device maintenance, and troubleshooting. The Sunrise SDDA system is not intended as a substitute for full polysomnography nor intended to be used as an apnea monitor. Installation will be carried out by the patient, according to installation instructions and verification procedures provided by Sunrise.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a device for sleep apnea testing based on mandibular movement and the measures necessary to mitigate these risks.

Identified Risks to Health	Mitigation Measures
Delayed or incorrect treatment due to erroneous output as a result of software malfunction or algorithm error	Software verification, validation, and hazard analysis Clinical performance testing Labeling
Delayed or incorrect treatment due to user misinterpretation	Labeling
Delayed or incorrect treatment due to sensor failing to provide inputs for software to adequately analyze	Software verification, validation, and hazard analysis Clinical performance testing Labeling
Electrical shock, burn, or interference with other devices	Electrical safety testing Electromagnetic compatibility (EMC) testing

	Labeling
Adverse tissue reaction	Biocompatibility evaluation

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the devices for sleep apnea testing using physiological signals not standard in clinical sleep studies is subject to the following special controls:

(1) Clinical data must be provided. This assessment must fulfill the following:
   (i) The clinical data must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified.
   (ii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.
   (iii) The assessment must compare device performance with a clinical comparator device (e.g., polysomnography).

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) The performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical, mechanical, and thermal safety of the device.

(4) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must include:
   (i) A full characterization of the software technical parameters, including algorithms;
   (ii) A description of the expected impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications; and
   (iii) A description of all mitigations for failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(5) Labeling must include:
   (i) A description of what the device measures and outputs to the user;
   (ii) Warnings identifying sensor acquisition factors or subject conditions or characteristics (e.g., conditions affecting the anatomy of the recording site, or subject conditions that may affect mandibular movement) that may impact measurement results;
   (iii) Guidance for interpretation of the measurements, including a statement that the device is not intended as a substitute for full polysomnography nor intended to be used as an apnea monitor; and
   (iv) The expected performance of the device for all intended use populations and environments.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in clinical studies described above.

The consequences of a false negative result would be a delay in patient management and may lead to deterioration of the patient's health. Since OSA is a chronic condition that affects quality of life in the long term, the risk severity of false negative results is significant. However, per AASM guidelines, it is recommended that if a single home sleep apnea test is negative, inconclusive or technically inadequate, PSG be performed for the diagnosis of OSA. Sunrise SDDA device is a prescription use device and results are only intended to be used by the clinician as an aid in diagnosis of OSA. Therefore, the Sunrise SDDA system is to be used in combination with all available information to make patient management decisions and a false negative result would not likely lead to patient injury. Also, since OSA is usually diagnosed after several years, a short delay of a few weeks can be insignificant. The Sunrise SDDA system utilizes a new technology for aiding in automated evaluation of OSA using mandibular movement signals. While movement signals from the mandible are not among conventional PSG channels, and clinical interpretation of raw data may not be feasible by physicians, the device has been validated to have clinically acceptable accuracy and the probability of a patient harm related to false results is minimal.

The probable benefits of the device are also based on data collected in clinical studies as described above.

The device can benefit the patient by providing an easy-to-use and more accessible tool to aid in OSA diagnosis in order to initiate treatment or seek further diagnosis. In certain settings and circumstances, a home sleep apnea testing (HSAT) device like Sunrise SDDA device offers a more practical, and faster alternative to the conventional way of overnight in-lab PSG. Compared to the standard in-lab PSG, Sunrise SDDA device provides users with favorable sleeping conditions at home to overcome in-lab PSG issues such first-night effects and undesired sleep position because of electrodes and wires, etc. Sunrise SDDA device can also shorten the management time for referring patients to the specialists by providing automated notification of OSA severity and other sleep structure parameters within 48 hours of testing.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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 probable benefits outweigh the probable risks for the Sunrise SDDA device. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Sunrise SDDA device is granted, and the device is classified as follows:

Product Code: QRS
Device Type: Device for sleep apnea testing based on mandibular movement
Regulation Number: 868.2376
Class: II