



January 07, 2022

Sunrise SA
Francois Naye
QA/RA Manager
Chaussée de Marche 598/02
Namur, 5101
Belgium

Re: DEN210015

Trade/Device Name: Sunrise Sleep Disorder Diagnostic Aid
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 25, 2021
Received: April 2, 2021

Dear Francois Naye:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Sunrise Sleep Disorder Diagnostic Aid (SDDA), a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Sunrise Sleep Disorder Diagnostic Aid, and substantially equivalent devices of this generic type, into Class II under the generic name device for sleep apnea testing based on mandibular movement.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On April 2, 2021, FDA received your De Novo requesting classification of the Sunrise Sleep Disorder Diagnostic Aid. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Sunrise Sleep Disorder Diagnostic Aid into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Sunrise Sleep Disorder Diagnostic Aid can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

In combination with the general controls of the FD&C Act, the device for sleep apnea testing based on mandibular movement 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.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the device for sleep apnea testing based on mandibular movement they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Farid Yaghouby at 240-402-2520.

Sincerely,

for Malvina B. Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,

Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health