February 24, 2022

Ectosense nv
Bart Van Pee
Product Manager
Bosbessenlaan 19A
Rotselaar, Vlaams Brabant 3110
Belgium

Re: K220028
Trade/Device Name: NightOwl
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: January 27, 2022
Received: January 28, 2022

Dear Bart Van Pee:

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, 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: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220028

Device Name
NightOwl

Indications for Use *(Describe)*
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 use under the direction of a Healthcare Professional (HCP).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

NightOwl

1. SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE PREPARED

Ectosense *nv*
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3110
Belgium

Phone: +32 496 74 46 12

Contact Person: Bart Van Pee

Date Prepared: 23th of February 2022

2. DEVICE

Name of Device

NightOwl

Trade Name

NightOwl

Common or Usual Name

Ventilatory Effort Recorder

Classification Name/Product Code/CFR Reference

Class II, Ventilatory Effort Recorder, Product Code: MNR; 21 CFR 868.2375

3. PREDICATE DEVICE

Predicate: Ectosense's NightOwl (K213463)

4. DEVICE DESCRIPTION

The NightOwl is prescribed by a Health Care Professional for the patient to use in the home as a 'home sleep apnea test' (HSAT).

The NightOwl comprises a sensor that is worn on the fingertip (the "NightOwl Sensor") over-night whilst the subject is sleeping and cloud-based analysis software (the "NightOwl Software").

The NightOwl Sensor has a small biocompatible enclosure. The sensor has 2 LEDs, one in the red spectrum and the other in the infrared spectrum, and an accelerometer. The sensor is attached to the fingertip by single-use biocompatible adhesive tape, with the sensor window applied against the fingerprint area of the fingertip. The sensor measures the reflected red/infrared signals to record the photoplethysmograph (PPG) signal. The accelerometer is used to detect movement.

The data recorded by the NightOwl Sensor can either be stored in on-board memory ("Offline" mode) or streamed via a Bluetooth link to an Ectosense app on a smartphone ("Streaming" mode)

- If the data is stored on the device, the data is retrieved when the NightOwl sensor is returned to the prescribing HCP and passed up to a cloud-based signal processing suite, the NightOwl Software.
- If the device is used in Streaming mode, the data is stored by the Ectosense app on the smartphone during the recording. At the end of the recording, it is then passed directly up to the cloud-based signal processing suite.
- The NightOwl Software signal processing algorithms produce a number of sleep and sleep-disordered breathing related traces and parameters. The trace and parameter information are passed to a company-managed database for storage and access by the prescribing Health Care Professional in the Ectosense Dashboard.

5. INTENDED USE

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 use under the direction of a Healthcare Professional (HCP).

6. DEVICE MODIFICATIONS

We expanded the sleep time outputs by adding the Total REM Time to the already cleared Total Sleep Time (TST) as output of the device. The Total REM Time was validated using the identical method and protocol used to validate the TST supporting the previously cleared 510(k).

Characteristic	NightOwl (K213463)	NightOwl (Current Device)	Comparison
Intended Use/ Indications for Use	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 use under the direction of a Healthcare Professional (HCP).		Equivalent
Intended Environment	Recording in the home environment with the report interpretation performed in the clinical setting.		Equivalent
Prescription	Prescription only		Equivalent
Target Population	22 years old and older		Equivalent
Channels	1. PAT 2. Pulse rate 3. Oximetry 4. Actigraphy		Equivalent
Sensors	Optical plethysmography sensor, accelerometer		Equivalent
Wearable sensor location	The photoplethysmography (PPG) sensor and accelerometer components are worn on the fingertip.		Equivalent
Sensor Software	Firmware is limited to control the recording and communications processes. No presentation of test results to the patient. Data analyzed and presented in a separate software suite.		Equivalent

Analysis Software - location	Analysis performed off the recording device, exclusively cloud-based by the NightOwl software.		Equivalent
Analysis Software – algorithm -pAHI	pAHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea AND pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea		Equivalent
Analysis Software – algorithm -Sleep Time	Total Sleep Time (TST) calculation	Total Sleep Time (TST) calculation, and, Total REM Time calculation	Substantially equivalent The addition of Total REM Time does not alter the device's intended use and does not introduce any change to the safety and effectiveness of the originally cleared device (predicate device). As such, the algorithm of the altered device remains substantially equivalent to that of the originally cleared device (predicate device)
Data transfer	Data transfer through a smartphone by wireless connection.		Equivalent
Power Source recorder	Battery powered by coin cell		Equivalent
Patient isolation	Device has no galvanic connections to mains as it is a battery-operated device.		Equivalent
Sterilization	Non-sterile		Equivalent
Bio-compatibility	Assessed to ISO1099-1:2009 requirements for sensitization, irritation, and cytotoxicity		Equivalent
EMC	IEC 60601-1-2:2014		Equivalent
Electrical Safety	IEC 60601-1:2005 +AMD1:2012		Equivalent
Environmental Testing	IEC 60601-1-11:2010		Equivalent

7. PERFORMANCE DATA

Software validation: In support of the substantial equivalence determination of the modification made to the device, software validation was performed.

Clinical Study: The clinical validation of the NightOwl performance for Total REM Time determination was compared to the gold standard polysomnography (PSG) in a US population. The following table highlights the performance of the subject device.

Endpoint parameters	**Performance of modified device (Subject)**
Patient population size	71
Total REM Time root mean square difference	22.72 minutes
Total REM Time correlation	0.51
Total REM Time Bias	-1.96 minutes
Total REM Time Upper Limit of Agreement	42.72 minutes
Total REM Time Lower Limit of Agreement	-46.64 minutes

8. CONCLUSIONS

Based on (i) the results of the clinical validation testing, (ii) the results of the software validation testing, and (iii) the unchanged product risk analysis, the NightOwl has been demonstrated to be substantially equivalent to the predicate device.