



December 16, 2021

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

Re: K213463  
Trade/Device Name: NightOwl  
Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing frequency monitor  
Regulatory Class: Class II  
Product Code: MNR  
Dated: October 26, 2021  
Received: October 27, 2021

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](mailto: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

## Indications for Use

510(k) Number (if known)

K213463

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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(k) SUMMARY

### NightOwl

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

Ectosense *nv*  
Bosbessenlaan 19A  
Rotselaar  
Vlaams-Brabant  
3110  
Belgium

Phone: +32 496 74 46 12

Contact Person: Bart Van Pee

Date Prepared: 15<sup>th</sup> of December 2021

#### **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 068.2375

### **3. PREDICATE DEVICE**

Predicate: Ectosense's NightOwl (K191031)

### **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 / 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).

## 6. DEVICE MODIFICATIONS AND COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

We have now incorporated an alternative tuning of the NightOwl algorithm to include hypopnea as scored using the 1B rule. The HCP can now choose to display either the 1A-tuned or the 1B-tuned pAHI (or both) on the NightOwl Examination report. As per the American Academy of Sleep medicine (AASM):

**1A rule:** a hypopnea is scored when:

1. There is an airflow reduction of 30% for at least 10 seconds
2. There is an oxygen desaturation of at least **3 percent or an arousal**.

**1B rule:** a hypopnea is scored when:

1. There is an airflow reduction of 30% for at least 10 seconds
2. There is an oxygen desaturation of at least **4 percent**

Characteristic	NightOwl (K191031)	NightOwl (K213463)	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	<ol style="list-style-type: none"> <li>1. PAT</li> <li>2. Pulse rate</li> <li>3. Oximetry</li> <li>4. Actigraphy</li> </ol>		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 calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea	<p>pAHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea</p> <p>AND</p> <p>pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea</p>	<p>Substantially equivalent</p> <p>Addition of pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea</p> <p>The addition of the pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea 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).</p>
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 using 1B rule was compared to the gold standard polysomnography (PSG) in the US population. The following table compares the performance of the subject and predicate devices.

Endpoint Parameters	1A rule performance of originally cleared device (Predicate K191031)	1B rule performance of modified device (Subject)
Sensitivity at AHI cutoff 5	0.936	1.000
Specificity at AHI cutoff 5	0.727	0.823
Sensitivity at AHI cutoff 15	0.978	0.973
Specificity at AHI cutoff 15	0.704	0.886
Sensitivity at AHI cutoff 30	0.964	0.840
Specificity at AHI cutoff 30	0.844	0.979
pAHI correlation	0.909	0.946

## 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.