March 6, 2020

Ectosense nv
Bart Van Pee
COO
Bosbessenlaan 19A
Rotselaar, 3110 BE

Re: K191031
Trade/Device Name: NightOwl
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: February 3, 2020
Received: February 3, 2020

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,

for Michael Ryan
Division Director
DHT1C: Division of ENT, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191031

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.

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I. 510(K) SUMMARY

510(k) SUMMARY

Ectosense *nv*'s NightOwl

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

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

Phone: +32 2 588 9044

Contact Person: Bart Van Pee

Date Prepared: 06 March 2020

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: Itamar Medical Ltd's WatchPAT 200U (K161579)

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 Ectosense NightOwl comprises a sensor that is worn on the fingertip (the "NightOwl Sensor") and cloud-based analysis software (the "NightOwl Software").

The NightOwl Sensor is a small biocompatible enclosure with a sensor window made from PMMA (bottom part) and ABS (top part). 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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the NightOwl and the predicate WatchPAT 200U are built around fingertip mounted optical plethysmography (PPG) measurements and incorporate an accelerometer for detection of limb movement. The accelerometer is used to estimate when the wearer is asleep by actigraphy methods. The PPG sensor produces a signal that is further analyzed to produce an SpO_2 measurement and pulse rate. The variations in the PPG amplitude, SpO_2, and pulse rate are then used to determine apnea and hypopnea events and thus indicate the patient's AHI for that night.

The variations in PPG amplitude reflect pulsatile volume changes in the peripheral tissue that reflect changes in Peripheral Arterial Tone ("PAT"). As both devices analyze such changes in peripheral arterial tone from the fingertip, the AHI value is characterized as "peripheral AHI" or "pAHI". The sleep reports presented to the prescribing HCP also contain derived sleep-related parameters such as estimated Total Sleep Time (TST) and maxima and minima of parameters to provide general sleep information to the HCP.

The NightOwl and its predicate are based upon the similar technological elements:

- Fingertip optical plethysmography sensor
- Accelerometer on the limb
- External signal processing
- Key output is pAHI

The below table compares NightOwl and WatchPAT devices.

Characteristic	Predicate Device WatchPAT 200U	NightOwl	Comparison
Intended Use/ Indications for Use	The WatchPAT 200U (WP200U) device is a non-invasive home care device	The NightOwl is a wearable device intended for use in the recording,	Substantially equivalent.

Characteristic	Predicate Device WatchPAT 200U	NightOwl	Comparison
	for use with patients suspected to have sleep related breathing disorders. The WP200U is a diagnostic aid for the detection of sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP200U generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHIc"), PAT sleep staging identification (PSTAGES) and optional snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP200U's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHIc. The WP200U's PSTAGES and snoring level and body position are not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. PAHIc is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.	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).	The NightOwl's Intended Use and Indications for Use does not include sleep staging, snoring level, body position, or the discrimination between central and obstructive sleep apneic events. The NightOwl is only intended for use in an adult patient population.
Intended Environment	Recording in the home environment with the report interpretation performed in the clinical setting.		Equivalent.

Characteristic	Predicate Device WatchPAT 200U	NightOwl	Comparison
Prescription	Prescription only		Equivalent
Target Population	12 years old and older (for the main indications)	22 years old and older	Substantially equivalent. NightOwl target patient population is more restrictive.
Channels	1. PAT 2. Pulse rate 3. Oximetry 4. Actigraphy 5.Snoring and Body Position (SBP) integrated external sensor	1. PAT 2. Pulse rate 3. Oximetry 4. Actigraphy	Substantially equivalent in non-optional channels. The Predicate is provided with an optional external snoring and body position sensor which NightOwl does not provide.
Sensors (non-optional)	Optical plethysmography sensor, accelerometer		Substantially Equivalent
Wearable sensor location	Finger probe for PAT and SpO2 sensing components are worn on the finger. Embedded actigraphy that is located in a wrist-mounted enclosure.	The photoplethysmography (PPG) sensor and accelerometer components are worn on the fingertip.	Substantially equivalent The difference in location of the actigraphy components does not affect performance in sensing movement.
Device size	Wrist-mounted enclosure: 3.2” long x 2” wide x 0.8” deep (80x50x20 mm)	0.75” high x 1.1” wide x 0.4” thick (19x28x11mm)	Substantially equivalent.
Device weight	4 $^{19}/_{32}$ oz (130g) for wrist-mounted enclosure, $^{23}/_{32}$ oz (20g) for finger probe	$^{7}/_{32}$ oz (6g)	Substantially 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.		Substantially equivalent
Analysis Software - location	Analysis performed off the recording device, on the PC or cloud-based by the zzzPAT software.	Analysis performed off the recording device, exclusively cloud-based by the NightOwl software.	Substantially equivalent. The Predicate allows for local analysis on a PC, where NightOwl only allows for cloud-based processing.

Characteristic	Predicate Device WatchPAT 200U	NightOwl	Comparison
Data transfer	Data transfer through a PC by means of USB cable.	Data transfer through a smartphone by wireless connection.	Substantially equivalent. The Predicate uses the PC while the NightOwl uses the smartphone as a data forwarder.
Memory	Embedded flash memory, 64 MB		Equivalent.
Power Source recorder	Internal rechargeable li-ion battery		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 60601-1-11:2015	IEC 60601-1-11:2010	Substantially equivalent.

7. PERFORMANCE DATA

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

Biocompatibility Testing

The biocompatibility evaluation for the NightOwl device was conducted in accordance with 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”, as recognized by FDA, with passing results. The tests conducted were:

- Cytotoxicity
- Sensitization
- Irritation

Electrical Safety and Electromagnetic Compatibility (EMC)

The Ectosense NightOwl has been tested to the relevant parts of the following recognized performance standards:

- IEC60601-1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- IEC60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

The NightOwl complied with all of the requirements of the performance standards for use in the home environment.

The following additional testing was carried out:

- RF immunity in the presence of Home RF emitters: A cell phone, when it is closer than 10 feet away, may emit RF fields in excess of those tested by IEC60601-1-2. A bench test was carried out to demonstrate that the NightOwl was unaffected by common household RF emitters that were within 3 feet of it.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Clinical Studies

The three clinical studies of the NightOwl consisted of:

SpO_2 measurement accuracy: To validate the accuracy of the NightOwl derived SpO_2 values and the pulse rate (PR) trace in accordance with *ISO 80601-2-61:2019 201.12.1.101.2* and *Annex EE.2* as recommended by the *FDA Guidance for Industry and FDA Staff Pulse Oximeters – Premarket Notification Submissions [510(k)s].* The NightOwl's pulse oximeter function was within the pass/fail criteria as described in *ISO80601-2-61:2019 Clause 201.12.1.101.1.* The pulse rate root mean square (RMS) value was found to be 2.26 beats per minute (bpm) for a claimed range of 50 to 118 bpm.

Comparison to PSG Sleep Lab Results: The clinical validation of the NightOwl accuracy in the calculation of pAHI when compared to the gold standard analysis of the polysomnography (PSG). This trial was conducted in Belgium. It was evidenced that the NightOwl sensitivity and specificity at an AHI cutoff 5 were 0.943 and 0.813, respectively.

Comparison to United States PSG Sleep Lab Results: A repeat study of the PSG comparison trial conduced in the United States to confirm that the NightOwl's pAHI accuracy is similar when the device is used in a US population. It was evidenced that the NightOwl sensitivity and specificity at an AHI cutoff 5 were 0.936 and 0.727, respectively.

Summary of AHI accuracy results: The AHI accuracy results of the pooled analysis containing the patients from the clinical trials in the United States and Belgium can be summarized as follows:

- Regression line with $AHI_{(Expert\ PSG)} = 0.9981 \times pAHI_{(NightOwl)} + 2.235$

8. CONCLUSIONS

Based on the performance data and testing in conformance to consensus standards, the NightOwl has been demonstrated to be substantially equivalent to the predicate device.