July 15, 2022

Neurotronics, Inc.
James "Cody" Smith
Quality Manager
4500 NW 27th Ave, Ste. C2
Gainesville, Florida 32606

Re: K220631
Trade/Device Name: NomadAir PMU810
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, MNR
Dated: June 3, 2022
Received: June 15, 2022

Dear James "Cody" Smith:

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
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K220631

Device Name
NomadAir PMU810

Indications for Use *(Describe)*
The NomadAir PMU810 is intended to record physiological signals acquired from a patient for archival in a sleep study. Data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep-disordered breathing (SDB).

The NomadAir PMU810 is intended for use within a hospital, laboratory, clinic, nursing home, or patient's home.

The NomadAir PMU810 is intended for use on adults only under the direction of a physician or qualified sleep technician.

The NomadAir PMU810, or any accessory, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,
* an alarm or alarm system;
* an apnea monitor or apnea monitoring system; or
* a life monitor or life monitoring system.

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
PRAStaff@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

1 General Information

Preparation Date: 2-18-22

Submitter/Holder

Neurotronics®, Inc.
4500 NW 27th Ave STE C2
Gainesville, FL 32606

Tel: (352) 372-9955

Website: https://www.neurotronics.com/

Primary Contact Person:
Name: James "Cody" Smith

Title: Quality Manager

Phone: (352) 372-9955 Ext. 515

Email: quality@neurotronics.com

2 Regulatory Information

Subject Device Name	NomadAir PMU810
Classification Names	Amplifier, Physiological Signal
Device Classification	II
Common Name	Portable Sleep Recorder
FDA Product Code	GWL, MNR
CFR References	21 CFR 882.1835
Review Panel	Neurology

3 Identification of Predicate Device

From a regulatory perspective, Neurotronics®, Inc. regards the NomadAir PMU810 to be substantially equivalent to other legally marketed devices including the predicate the NOMAD, Polysmith Sleep System K092699 and the Reference Device ApneaTrak K192624.

4 Subject Device Description

The NomadAir PMU810 is a portable device that records physiological signals used for sleep studies. The device can be worn on the chest or the wrist and is attached to the patient using a RIP belt or a disposable strap connected directly to the device. The patient also wears a pulse oximeter probe, a nasal cannula, and an optional sensor, such as a RIP belt, thermocouple, EMG electrode, or ECG electrode.

During the typical workflow of using the NomadAir, the clinical user configures the device for a patient. The clinician will give the patient instructions on how to attach the device and sensors and send the unit and accessories home with the patient. Before going to bed, the patient will connect everything, then go to sleep. The NomadAir records the signals from the sensors and saves the data to internal memory. The patient may perform up to 3 sleep studies before returning the device. Once the clinician receives the device, they can connect it to a PC using a USB cable and download the study for analysis.

5 Indications for Use

Per the current proposed product labeling, the indications for use for the NomadAir PMU810 are quoted as follows:

The NomadAir PMU810 is intended to record physiological signals acquired from a patient for archival in a sleep study. Data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep-disordered breathing (SDB).

The NomadAir PMU810 is intended for use within a hospital, laboratory, clinic, nursing home, or patient's home.

The NomadAir PMU810 is intended for use on adults only under the direction of a physician or qualified sleep technician.

The NomadAir PMU810, or any accessory, does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,

- an alarm or alarm system;
- an apnea monitor or apnea monitoring system; or
- a life monitor or life monitoring system.

Please note that the above indication is slightly reworded compared to the already cleared indications for the predicate NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699 and updated accordingly per current FDA Guidance. The indications for use statement also provides further clarification that is complementary to the cleared predicate indications for use.

6 Substantial Equivalence Discussion

Any modifications between the predicate device and the subject device are provided in detail in **this submission**, while the table below is a summary. The review of the indications for use and comparison characteristics provided in **Table 1** demonstrate that NomadAir PMU810 is substantially equivalent to the predicate device, NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699 and the reference device ApneaTrak K192624.

Table 1. Summary Comparison of Characteristics

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Product Name	NomadAir PMU810	NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800	ApneaTrak	N/A-Differences do not impact safety or efficacy.
Manufacturer	Neurotronics®, Inc.	Neurotronics®, Inc.	Cadwell Industries, Inc	N/A-Differences do not impact safety or efficacy.
FDA Product Code	GWL, MNR, DQA	GWL, MNR, DQA	OLV, MNR	Substantially Equivalent across the predicate and reference devices.
CFR Reference	21 CFR 882.1835	21 CFR 882.1835	21 CFR 882.1400	Same as predicate
Device Class	II	II	II	Same
510(k) reference	TBD	K092699	K192624	N/A-Differences do not impact safety or efficacy.
Prescription or OTC	Prescription Only	Prescription Only	Prescription Only	Same
Implanted Device	No	No	No	Same

Indications for use statement	The NomadAir PMU810 is intended to record physiological signals acquired from a patient for archival in a sleep study. Data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep-disordered breathing (SDB). The NomadAir PMU810 is intended for use within a hospital, laboratory, clinic, nursing home, or patient's home. The NomadAir PMU810 is intended for use on adults only under the direction of a physician or qualified sleep technician. The NomadAir PMU810, or any accessory, does not include or trigger alarms, and is not intended to be	The Nomad device is intended to amplify and record physiologic potentials used for Polysomnography (PSG) or Sleep Studies. The bio-potentials are transferred to Polysmith polysomnography software running on a personal computer. Qualified practitioners use the information to score Polysomnograms and diagnose Sleep Disorders. The device is intended for use on both adults and children under the direction of a physician or qualified sleep technician. The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study, such as Limb Movement, Body Position, Respiration Effort, and SpO2. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal	The Cadwell ApneaTrak device is intended for home sleep testing, including the acquisition of physiological and environmental data. The recorded signals are then transmitted to a PC so that they can be viewed. ApneaTrak is intended for use on patients older than 2 years of age. ApneaTrak is intended for use in hospitals, sleep centers and other sleep testing environments, including the patient's home. ApneaTrak is intended to be used when prescribed by a qualified healthcare provider for use on patients suspected of sleep disorders, specifically Sleep Disordered Breathing (SDB) and requires review by qualified medical personnel. ApneaTrak is NOT intended to perform automatic diagnosis.	Substantially Equivalent - Minor wording differences do not impact safety or efficacy.

	used alone as, or a critical component of, • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • a life monitor or life monitoring system.	computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders. This device, or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system. This device, or any accessory, is not to be used alone as a life support device or as a critical component of a life support system. The device is not sterile		

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Target Population	Adults	Adults and Children	Patients 2 years and older	**Modified -** Removing children from the target population does not impact safety or efficacy for adults.
Environment for Use	* hospital * laboratory * clinic * nursing home * patient's home	* medical facility * physician's office * laboratory * clinic * nursing home * Outside a medical facility under direct supervision of a medical professional	Home or clinical environment	Substantially Equivalent - Home use is specified in the subject device rather than generic statement of outside of a medical facility. This is substantially equivalent.
Reusable or Single Use	Reusable	Reusable	Reusable	Same
Sold Sterile or Non-Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Physical Characteristics	* Weight: 135g * Size: 103mm x 74mm x 28mm * Enclosure Material: Medical Grade ABS Plastic	* Weight: 176g * Size: 125mm x 71mm x 25mm * Enclosure Material: ABS Plastic	* Weight: 143.5g * Size: 115 mm X 73 mm X 25 mm * Enclosure Material: ABS Plastic	Substantially Equivalent - Slight variations in size and weight do not impact safety or efficacy.
Power Source	Battery powered using 1 AA battery	Battery powered using 2 AA batteries	Internally powered using li-ion rechargeable battery	Substantially Equivalent - All devices powered with different types of battery.

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Patient Isolation	Device is battery-powered with no connection to mains during patient use.	Device is battery-powered with no connection to mains during patient use.	Device is battery-powered with no connection to mains during patient use.	Same
Primary Communications Interface	USB	USB	USB	Same
Wireless Interface	* LTE * Bluetooth - transmitter equipped, but disabled	* Bluetooth	* Bluetooth - transmitter equipped, but disabled	Modified - The difference between Bluetooth and LTE does not impact safety or efficacy because both interfaces are FCC approved modules. Additionally, the wireless interface does not impact the intended use of the device.

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Number of Channel Inputs	4	8	8	Modified - The subject device has less channels than the predicate. The subject device has 1 respiratory channel compared to 3 respiratory channels on the predicate, 1 poly channel to 2 EMG channels, and does not have a DC channel. These channels on the predicate are extra and are not required for home sleep studies. Their absence does not impact safety or efficacy.
Mode of Operation	Device is attached to a strap that secures the device while on the patient.	Device goes into a pouch which is secured with a strap.	Device is attached to a strap that secures the device while on the patient.	Substantially Equivalent

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Connections to Patient	* RIP belt for respiratory effort * Probes for pulse oximetry * Plastic cannula for pressure sensing * Poly channel supports standard sleep sensors/electrodes	* Probes for pulse oximetry * Plastic cannula for pressure sensing * Device inputs support standard sleep sensors	* RIP or PVDF belts for respiratory effort * Probes for pulse oximetry * Plastic cannula for pressure sensing * Plastic snore microphone	Modified - Predicate does not support direct RIP belt connection, but reference device does. RIP belt can still be used with predicate, but it requires it to be connected to a RIP driver that is connected to the device. Differences do not impact safety or efficacy.
Display Type	LEDs on device for sensor connection and device status	LED on device for device status	LEDs on device for signal check and device status	Substantially Equivalent - Predicate does not have LEDs for signal check, however reference device does.
Internal Memory/ Data Storage	Internal FLASH memory	Fixed microSD card	On-board storage	Substantially Equivalent - Memory is not removable in all devices. Difference in storage type does not impact safety or efficacy.
Recording Time	Up to 24 hours	Up to 24 hours	Up to 24 Hours	Same

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Channels / Signals Recorded	Channels * SpO2 * Pulse * Airflow or Nasal/Mask Pressure * Snore (Derived) * Respiratory Effort * Body Position * Activity * Poly (Can be used for Leg Movement, Respiratory, EMG, ECG, etc.)	Channels * SpO2 * Pulse * Airflow * Snore (Derived) * Respiratory Effort * Body Position * Leg Movement * DC	Channels * SpO2 * Pulse * Airflow * Nasal/Mask Pressure * Snore * Respiratory Effort * Body Position * Activity * EEG, EOG, EMG, ECG	Modified - Subject device does not have a DC channel, but neither does the reference device. Subject device has an Activity channel, as does the reference device. Subject device does not have an EEG channel, but neither does the predicate. None of these channels are required channels for home sleep studies.
Sensor Technology	* Silicon pressure sensor * MEMS accelerometer position/activity sensor * Pulse oximetry * Integrated RIP driver for respiratory effort * Poly input supports common sleep sensors	* Silicon pressure sensor * Mechanical position sensor * Pulse oximetry * Inputs support common sleep sensors	* Solid state pressure sensor * Solid state position/activity sensor * Pulse oximetry * Respiratory effort sensors (RIP or PVDF technology) * Snore Microphone * Gold cup electrodes * Ag/AgCL electrodes	Modified - Subject device uses a MEMS accelerometer, which is a type of solid-state sensor, like the reference device. Subject device also has an internal respiratory effort sensor, as does the reference device. Subject device does not have snore or EEG technologies, but neither does the predicate. None of these differences impact safety or efficacy.

Device Characteristic	**Proposed Device NomadAir PMU810**	**Primary Predicate Device NOMAD SLEEP SYSTEM RECORDER, MODEL PMU800, K092699**	**Reference Device ApneaTrak, K192624**	**Comparison Analysis:** *Same/ Substantially Equivalent / Modified / Not Applicable*
Access to recorded data	Recorded data stored in the device. When the device is connected to a PC via USB cable, the device provides access to the data through a file transfer protocol.	Recorded data stored in the device. When the device is connected to a PC via USB cable, the device provides access to the data through a file transfer protocol.	Recorded data is stored in the device. When the device is connected to a PC via USB cable, the device provides access to its internal memory.	Substantially Equivalent - Data is accessed through connection to a PC via USB cable. Subject and predicate devices do not have direct access to internal memory, just the ability to transfer the data. Difference does not impact safety or efficacy.
Recorded data format	All channels of recorded data are stored in device-specific format.	All channels of recorded data are stored in device-specific format.	All channels of recorded data are stored in EDF data format.	Substantially Equivalent - Differences in data format do not impact safety or efficacy.

7 Software

The development of the NomadAir complies with IEC 62304 Standard– medical device software – software life cycle processes.

8 Sterilization and Shelf Life

The NomadAir PMU810 does not have a claimed shelf life, therefore this section is not applicable.

The NomadAir PMU810 is sold non-sterile. Therefore, this section is not applicable.

9 Biocompatibility

The NomadAir PMU810 is intended to be worn for less than 24 hours, and no material is made with natural rubber latex. Additionally, the device enclosure is made from a medical-grade resin (Lustran 348) that meets the requirements of ISO 10993 for short-term skin contact. Biocompatibility testing was not performed specifically for this submission.

10 Performance Testing - Bench

Performance bench tests of NomadAir PMU810 have been performed, see **Table 2**. The results from the performance bench testing demonstrate that NomadAir PMU810 has met the functional requirements and is substantially equivalent to the predicate device. Performance bench testing is provided in detail in **this submission.**

Table 2. Performance Testing Summary

Study	Acceptance Criteria	Results
AC Signal Accuracy	Accuracy of recorded signal is +/- the greater of 5 uV or 5%.	Pass
CMRR Test	Poly channel shows CMRR >= 90 dB.	Pass
Input Impedance	Pass specification: Input impedance >=20 MOhm	Pass
Pressure Sensor Test	Accuracy of pressure sensor is +/- 1 cmH2O.	Pass
Body Position Test	Confirm all transition and hysteresis angles are within specifications	Pass
Sampling Rate Test	Base sampling rate is 250 Hz +/- 0.05%	Pass
Oximetry Test	Channel shows valid reading when sensor is correctly applied to subject. Channel shows zero when probe is disconnected or removed from subject.	Pass
Wireless Communication Test	Device transmits event driven status message and timed snapshot status messages successfully.	Pass
Data Transfer Speed Test	Files transfer in <1 minute per 8 hours of recorded data.	Pass
Pressure Sensor Accuracy Test	Accuracy of pressure sensor is +/- 1 cmH2O when the temperature is at 5 °C and 40 °C (+/- 3 °C)	Pass
Bootloader Test	Device starts into bootloader when powered on by USB with user button held pressed.	Pass
Input Noise Test	RIP and Poly channels have <= 6 uVp-p of input noise (0.53 Hz to 60 Hz)	Pass
Battery Life Test	NomadAir records for a minimum of 24 hours after 72 hours of standby time	Pass

Study	Acceptance Criteria	Results
Operating Modes and Indicator Test	All LED indicators display correctly in all modes.	Pass
Cleaning Test	After performing cleaning cycles that represent typical device usage over the expected service life, device is not damaged and passes dielectric strength test.	Pass
Data File and Storage Test	Log events are saved with the data with the correct timestamp.	Pass
Power Interruption Recovery Test	Device recovers from power interruption by resuming state prior to interruption for all operating modes.	Pass
Power Interruption From Rough Handling	Device suffers no power interruption when handled roughly	Pass
RIP Driver Test	Peak to trough measurement is greater than 750 uV for 1" deflection of belt. Peak to trough noise is within -40 to 40 uV	Pass

11 Conclusion

The subject device NomadAir PMU810 is substantially equivalent to the predicate device. NomadAir PMU810 shares a substantially equivalent design, indications for use and technology (i.e. features, materials, and principles of operation) with the predicate device and no new elements pertaining to safety or effectiveness have been identified.