February 20, 2020

Cadwell Industries, Inc.
Mr. James Blevins
Product Manager - Sleep
909 N. Kellogg Street
Kennewick, Washington 99336

Re: K192624
Trade/Device Name: ApneaTrak
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, MNR
Dated: January 7, 2020
Received: January 21, 2020

Dear Mr. James Blevins:

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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K192624

Device Name
ApneaTrak

Indications for Use *(Describe)*
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.

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.

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*"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

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|---|---|
| ***Submitter:*** | Cadwell Industries, Inc.<br>909 N. Kellogg Street<br>Kennewick, Washington 99336<br>509-735-6481 |
| ***Contact Person:*** | James Blevins<br>Email: jamesbl@cadwell.com |
| ***Date Prepared:*** | September 20, 2019 |
| ***Trade Name:*** | ApneaTrak |
| ***Regulation Name:*** | Standard Polysomnograph with Electroencephalograph |
| ***Regulation Number:*** | 21 CFR 882.1400 |
| ***Regulatory Classification:*** | Class II |
| ***Product Codes:*** | OLV, MNR |
| ***Classification Panel:*** | Neurology |
| ***Predicate Device:*** | Primary Predicate:<br>Zmachine Synergy Sleep Monitoring System from Consolidated Research of Richmond, Inc.<br>Product Code: OLV, OMC, MNR<br>510(k) Number: K172986<br>Reference Predicate:<br>Nox T3 Sleep Recorder from Nox Medical<br>Product Code: MNR<br>510(k) Number: K082113 |
| ***Device Description:*** | Cadwell's ApneaTrak is a sleep diagnostic system consisting of: (1) acquisition hardware that can acquire, record, store, and transfer up to 3 channels of ExG (including EEG, EMG, ECG, and EOG signals) data, 2 respiratory effort channels, 1 thermistor channel, 1 pressure channel, 1 snore channel, and 1 oximetry channel; (2) a host electronic device (typically a PC) capable of running the software as well as charging |

and interfacing with the acquisition device; and (3) software that allows for device configuration and data download.
ApneaTrak is connected, by a clinical user, to a host device via USB cable for initialization. After initialization and having been given instruction on correct clinical use of the device, ApneaTrak is then used by the patient at home. The device acquires and stores physiological and/or environmental data to onboard memory. After use, the device is returned to the clinical user, who connects the device to the host PC. The software downloads and stores data from the device in European Data Format (EDF).

***Indications for Use:***

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.

***Technology Comparison:*** The ApneaTrak employs the same technological characteristics as the predicate devices.

| | Zmachine Synergy (K172986, Primary Predicate) | Nox T3 Sleep Recorder (K082113, Reference Predicate) | Cadwell ApneaTrak (Proposed Device) | Discussion of Differences |
|---|---|---|---|---|
| **General** | | | | |
| **Product Codes** | OLV, OMC, MNR | MNR | OLV, MNR | Equivalent |
| **Classification Regulation** | 21 CFR 882.1400 | 21 CFR 868.2375 | 21 CFR 882.1400 | Equivalent |
| **Population** | Adults | Greater than 2 years of age | Greater than 2 years of age | Differences in patient population do not raise concerns of safety or effectiveness. |
| **Prescription Use** | Yes | Yes | Yes | Equivalent |
| **Intended Environments** | Home or clinical environment | Home or clinical environment | Home or clinical environment | Equivalent |
| **Indication for Use** | The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified | The Nox T3 device is intended for ambulatory recording of physiological signals during sleep. The recorded signals are then downloaded to a PC where the signals can be viewed and analyzed by use of the Nox T3 application | 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 | The indications for use between the proposed device and the predicate have no substantive differences. |

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| | healthcare practitioner, to aid in the diagnosis of sleep disorders. | (Noxturnal). The Nox T3 system is indicated for use in patients greater than 2 years of age.<br>The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis.<br><br>The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home. | intended for use on patients older than 2 years of age.<br><br>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. | |
| **Physical** | | | | |
| **Case Material** | ABS Plastic | ABS Plastic | ABS Plastic | Equivalent |
| **Dimension** | 61mm (2.40") W<br>120mm (4.72) H<br>24mm (0.94") D | 80mm (2.5") W<br>111mm (4.9") H<br>18.5mm (0.8") D | 73mm (2.87") W<br>115mm (4.52") H<br>25mm (0.98") D | Differences in physical dimension do not raise concerns of safety or effectiveness. |
| **Weight** | 86g | 280g | 143.5g | Differences in physical dimension do not raise concerns of safety or effectiveness. |
| **Functional** | | | | |
| **Acquisition Units** | One unit | One unit | One unit | Equivalent |

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| **Number of Channel Inputs** | 6 | 7 | 8 | The proposed device has 2 additional EXG channel inputs. These additional EXG channels are composed of the same hardware and are controlled in the same manner as the other EXG channels. As such, whether the overall number of EXG channels is 2 or 3, the risk profile of the device does not change. Therefore, this difference does not raise concerns of safety or effectiveness. |
| **Recording Time** | Up to 30 hours | Up to 24 hours | Up to 24 hours | Differences in recording time do not raise concerns of safety or effectiveness. |
| **Data Storage** | On-board storage | On-board storage | On-board storage | Equivalent |
| **Data Interface (PC)** | USB | USB | USB | Equivalent |
| **Connections to Patient** | RIP belt for respiratory effort<br><br>Probes or Flexi wrap for oximetry<br><br>Plastic tubing and cannula for pressure sensing | RIP belt for respiratory effort<br><br>Probes or Flexi wrap for oximetry<br><br>Plastic tubing and cannula for pressure sensing | RIP or PVDF belts for respiratory effort<br><br>Probes for oximetry<br><br>Plastic cannula for pressure sensing<br><br>Plastic snore microphone | All accessories are previously cleared, widely available medical devices.<br>Differences do not raise questions of safety and effectiveness. |

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| **Display Type** | LEDs on device for signal check and device status | LCD on device for signal check and device status | LEDs on device for signal check and device status | Equivalent |
| **Signals and Sensors** | | | | |
| **Signals Recorded** | Respiratory Effort<br>Body position<br>Activity<br>Oxygen Saturation<br>Pulse<br>Airflow<br>Snore<br>EEG | Respiratory Effort (Abdomen and Thorax)<br>Body position<br>Activity<br>Oxygen Saturation<br>Pulse<br>Nasal/mask pressure<br>Airflow<br>Snore<br>EEG, EOG, EMG, ECG<br>Respiratory sound | Respiratory Effort (Abdomen and Thorax)<br>Body position<br>Activity<br>Oxygen Saturation<br>Pulse<br>Nasal/mask pressure<br>Airflow (Pressure and Thermal)<br>Snore<br>EEG, EOG, EMG, ECG | The addition of an independent snore sensor (both sensors derive snore from the cannula as well) and additional ExG inputs (3 vs 1) do not raise questions of safety or effectiveness as the channels are just multiplied to meet clinical user's needs.<br>Nasal/mask pressure is the same as pressure-based airflow and would be equivalent in the predicate despite not being listed. |
| **Sensor Technology** | Solid state pressure sensor<br>Solid state position/activity sensor<br>Respiratory effort sensors (RIP Technology)<br>Oximetry<br>Zmachine EEG Technology | Solid state pressure sensor<br>Solid state position/activity sensor<br>Respiratory effort sensors (RIP technology)<br>Oximetry<br>Microphone<br>Gold cup electrodes<br>Ag/AgCL electrodes | Solid state pressure sensor<br>Solid state position/activity sensor<br>Respiratory effort sensors (RIP or PVDF technology)<br>Oximetry<br>Snore Microphone<br>Gold cup electrodes<br>Ag/AgCL electrodes | Equivalent<br>ApneaTrak uses common ExG technology using gold or Ag/AgCL cup electrodes.<br>The predicate device uses a snap style connector. Electrode connection styles do not raise questions of safety or effectiveness as they are |

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| | | | | both used commonly in the industry. |
| **Power and Isolation** | | | | |
| **Power Source** | Internally powered using li-ion rechargeable battery | Internally powered using AA disposable battery | Internally powered using li-ion rechargeable battery | Equivalent |
| **Patient Isolation** | Device has no galvanic connections to mains during operation as it is a battery-operated device<br><br>Not possible to connect auxiliary devices to the device | Device has no galvanic connections to mains during operation as it is a battery-operated device<br><br>Not possible to connect auxiliary devices to the device | Device has no galvanic connections to mains during operation as it is a battery-operated device<br><br>Not possible to connect auxiliary devices to the device | Equivalent |
| **Transmitter** | | | | |
| **RF Data transfer** | None | Bluetooth wireless technology | Bluetooth Transmitter Equipped, but disabled | Bluetooth transmitter has been included as part of the ApneaTrak Hardware but is disabled by firmware/software at this time and is not available to the user. Bluetooth functionality is subject to future 510(k) clearance. Equivalent currently. |
| **Recorded Data** | | | | |
| **Access to recorded data** | 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. | 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. | 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. | Equivalent |

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| **Recorded data format** | Each channel of recorded data is stored in an individual file of the GCS2 data format. | All channels of recorded data are stored in proprietary data format. | All channels of recorded data are stored in EDF data format. | GCS2 appears to be the predicate device's proprietary data format. EDF is non-proprietary. Data format does not raise new concerns of safety or effectiveness. |
| **Device Initialization** | Yes | Yes | Yes | Equivalent |
| **Data Download** | Yes | Yes | Yes | Equivalent |

***Electrical Safety:***

The ApneaTrak was tested for safety and essential performance in accordance with the following safety standards:

- IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012
- AAMI ES60601-1:2005 +C1+A2 [R2012]
- IEC 60601-2-40:2016
- IEC 60601-2-26:2012
- ISO 80601-2-61:2017
- IEC 60601-1-11:2015
- IEC 60601-1-6:2013
- IEC 62304:2006 + A1:2015

Test results indicate that the ApneaTrak complies with the applicable standards.

***Electromagnetic Disturbances:***

The ApneaTrak was tested for performance in accordance with the following standards:

- IEC 60601-1-2:2014

Test results indicate that the ApneaTrak complies with the applicable standards.

***Performance Testing:***

The ApneaTrak was tested in accordance with internal software requirements, system requirements, and usability requirements as a result of the risk analysis External tests have been completed for electrical safety and EMC as indicated above. In addition, bench testing results are summarized below to demonstrate the ApneaTrak complies with its predetermined specifications and accurately captures each biologically relevant signal being collected by the predicate devices.

| Test | Test Method Summary | Results |
|---|---|---|
| ExG | ExG functionality of the subject device is validated by complying with essential performance requirements from the following standards: IEC 60601-2-26 and IEC 60601-2-40. | All tests results demonstrate compliance with the standards. |
| Pulse Oximetry | The pulse oximetry functionality of the subject device is validated by complying with ISO 80601-2-61 Particular requirements for pulse oximeters | All tests results demonstrate compliance with the standard. |

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| Respiratory Effort | A known oscillating input signal was injected into the respiratory channel of the subject device. The input and output data were plotted and quantitatively compared. | Passing result based on high measure of equivalence between input and output signals. |
| Airflow - Pressure | A known oscillating input signal was input to the airflow pressure channel of the subject device. The input and output data were plotted and quantitatively compared. | Passing result based on high measure of equivalence between input and output signals. |
| Airflow - Thermal | A known oscillating input signal was input to the airflow thermal channel of the subject device. The input and output data were plotted and quantitatively compared. | Passing result based on high measure of equivalence between input and output signals. |
| Snore | A known oscillating input signal was input to the snore channel of the subject device. The input and output data were plotted and quantitatively compared. | Passing result based on high measure of equivalence between input and output signals. |

All tests confirm the ApneaTrak meets the requirements for both the external tests and performance bench tests. Cadwell Industries, Inc has determined the ApneaTrak is Substantially Equivalent to the predicate devices.

***Conclusion:*** Verification and validation activities were conducted to establish the performance and safety characteristics of the ApneaTrak. The results of these activities demonstrate that the ApneaTrak is as safe, as effective, and performs as well as or better than the predicate devices.

Therefore, the ApneaTrak is considered substantially equivalent to the predicate devices.