September 4, 2024

SomnoMed Technologies Inc., doing business as REMware
% Seth Mailhot
Partner
Husch Blackwell LLP
1801 Pennyslvania Avenue, N.W., Suite 1000
Washington, District of Columbia 20006

Re: K240646
Trade/Device Name: DreamClear
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, MNR, DQA
Dated: August 5, 2024
Received: August 5, 2024

Dear Seth Mailhot:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Gupta -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240646

Device Name

DreamClear

Indications for Use *(Describe)*

DreamClear is intended for use on both adults and children to collect, amplify, and transmit physiological signals, including electroencephalogram (EEG), electrooculography (EOG), limb movement, respiration effort, air pressure, and peripheral oxygen saturation (SpO2). DreamClear is intended for use on the order of a physician and is non-sterile.

While primarily intended for use with dedicated polysomnography software to aid in the diagnosis of sleep disorders, DreamClear may be used to amplify physiological signals for any medical diagnostic procedure that does not involve:
- use alone as an apnea monitor or as a critical component in an apnea monitoring system; or
- use alone as a life support device or as a critical component of a life support 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.

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510(k) Summary

Submitted by REMware
Address: 601 South Harbor Island Boulevard, Suite 109
Tampa, FL 33602
Telephone: (813) 364-2670
Contact Name: Arun Ramabadran, CEO

Date Submitted: August 2, 2024

Trade Name: DreamClear
Common Name: Physiological Signal Amplifier

Primary Product Code / Regulation: GWL (21 C.F.R. 882.1835)

Secondary Product Codes: MNR, DQA

Predicate Device: Neurotronics, Inc., Nomad Sleep System Recorder, Model PMU800 (K092699)

Reference Device: Respironics, Inc., Alice PDx (K090484)

Description: DreamClear is a physiological signal amplifier and medical device data system that captures and streams various physiological parameters via Bluetooth for remote data analysis and diagnosis of sleep disorders. DreamClear features analog sensor interface circuits for Electroencephalograph (EEG), Electrooculography (EOG) and Electromyography (EMG) signals. Additionally, the device includes digital sensor interface circuits for nasal and oral airflow (breathing pattern), microphone (snoring), heart rate and blood oxygen saturation with pulse oximeter (SpO_2).

The DreamClear may be used in either a Basic Kit or Extended Kit configuration. The DreamClear device in its Basic Kit configuration includes the chest belt, pulse oximeter, and nasal cannula. The Basic Kit configuration has the following channels: thoracic effort, nasal pressure, pulse rate, SpO2, body position, and snore. The data recorded by the Basic Kit may be exported for optional display and analysis using third-party software products.

When the DreamClear device is used in the Extended Kit configuration, the additional channels of EEG and EOG are used, which gives the DreamClear a total of eight (8) channels.

Indications for Use: DreamClear is intended for use on both adults and children to collect, amplify, and transmit physiological signals acquired from a patient, including electroencephalogram (EEG), electrooculography (EOG), limb movement, respiration effort, air pressure, and peripheral oxygen saturation (SpO_2). DreamClear is intended for use on the order of a physician and is non-sterile.

While primarily intended for use with dedicated polysomnography software to aid in the diagnosis of sleep disorders, DreamClear may be used to amplify physiological signals for any medical diagnostic procedure that does not involve:

- use alone as an apnea monitor or as a critical component in an apnea monitoring system; or
- use alone as a life support device or as a critical component of a life support system.

Substantial Equivalence: Substantial equivalence of DreamClear is similar in intended use and functionality to the Nomad Sleep System Recorder, Model PMU800, manufactured by Neurotronics, Inc. (K092699), a digital amplifier capable of measuring bio-potential signals that may be incorporated into a Polysomnogram. The Alice PDx, manufactured by Respironics Inc., (K090484), a ventilatory effort recorder capable of measuring bio-potential signals that may be incorporated into a Polysomnogram, is included as a reference device to support the optional addition of EEG and EOG channels.

Functionality	Predicate - Nomad (K092699)	Reference – Alice PDx (K090484)	Submission – DreamClear	Substantial Equivalence Comments
510(k) Owner	Neurotronics, Inc.	Respironics Inc., Sleep & Home Respiratory Group	SomnoMed Technologies Inc.	N/A

Functionality	Predicate - Nomad (K092699)	Reference – Alice PDx (K090484)	Submission – DreamClear	Substantial Equivalence Comments
Indications for Use	The Nomad device is a digital amplifier capable of measuring bio-potential signals that may be incorporated into a Polysomnogram. 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, Respiration Effort, and SpO_2. The 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 disorders. This device is not to be used alone as an apnea monitor or as a critical component in an apnea monitoring system. This device is intended for use on both adults and children on the order of physician. 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.	The Alice PDx is a physiological data recorder intended to collect and record data from multiple physiological channels for use by clinical software used in polysomnography and sleep disorder studies. It is intended for use by or on the order of a physician. It is intended for use on adults in a supervised (hospital) or unsupervised (home) environment.	DreamClear is intended for use on both adults and children to collect, amplify, and transmit physiological signals acquired from a patient, including electroencephalogram (EEG), electrooculography (EOG), limb movement, respiration effort, air pressure, and peripheral oxygen saturation (SpO_2). DreamClear is intended for use on the order of a physician and is non-sterile. While primarily intended for use with dedicated polysomnography software to aid in the diagnosis of sleep disorders, DreamClear may be used to amplify physiological signals for any medical diagnostic procedure that does not involve: • use alone as an apnea monitor or as a critical component in an apnea monitoring system; or • use alone as a life support device or as a critical component of a life support system.	Indications for use is essentially the same as the predicate, with minor differences in wording and the identification of additional physiological signals amplified by DreamClear (EEG, EOG and air pressure).

Functionality	Predicate - Nomad (K092699)	Reference – Alice PDx (K090484)	Submission – DreamClear	Substantial Equivalence Comments
Intended Use	The device is intended to amplify and record physiologic potentials used for polysomnography or sleep studies. 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 amplify and record physiologic potentials used for polysomnography or sleep studies. The device is intended for use on adults under the direction of a physician or qualified sleep technician.	DreamClear is intended to amplify and transmit physiologic potentials used for polysomnography and related diagnostic procedures, other than apnea monitoring or life support. DreamClear is intended for use on both adults and children under the direction of a physician, qualified sleep technician or other medical professional.	Generally, same as predicate with additional language from "Indications for Use" excluding apnea monitoring and life support.
Patient Population	Adults and Children	Adults	Adults and Children	Same as predicate.
Environment of Use	Various	Use in both supervised (hospital) or unsupervised (home) environments	Use in both supervised (hospital) or unsupervised (home) environments	Same as predicate and reference.

Number of Channels	Records 11 channels: 2 effort, 2 flow, body position, SpO_2, Pleth wave, heart rate, leg movements and 1 DC channel	Ten (10) base channels, and up to twenty-one (21) channels with optional ECG and ExG yokes:
		• EEG, EOG, EMG, ECG
		• Nasal/oral Airflow
		• Snore
		• Thoracic and Abdominal Effort
		• Body Position
		• Pulse Oximetry, including:
		  ○ Oxygen Saturation (SpO_2)
		  ○ Pulse Rate
		  ○ Plethysmograph
			Records 6 or 8 channels:
			• EEG, EOG
			• Nasal airflow
			• Snore (Microphone),
			• Respiratory Thoracic Effort,
			• Body Position,
			• Pulse Oximetry, including:
			  ○ SpO_2
			  ○ Pulse Rate
				Differences in channels and signals does not present differences in safety and effectiveness.

Signal Amplification	Produces signals in a physiological range.	Produces signals in a physiological range.	Produces signals in a physiological range.	Same as predicate and reference.
Interface	Wireless Bluetooth	Secure Digital (SD) Card	Wireless Bluetooth	Same as predicate.
Data Storage	On system	On system (storage on SD card)	Storage on patient phone	Storage on patient phone does not present differences in safety and effectiveness.
Sterility	Nonsterile	Nonsterile	Nonsterile	Same as predicate and reference.

Substantial equivalence was also established through a testing protocol that used bench data to evaluate the performance of DreamClear. Testing demonstrated that DreamClear amplified

physiological signals sufficient for use with polysomnography software to aid in the diagnosis of sleep disorders, which is substantially equivalent to the intended use of the predicate Nomad device. A usability study established that DreamClear could effectively be used in a home setting by lay users. Testing, therefore, demonstrated that DreamClear is substantially equivalent to the predicate device.

In addition to the comparisons in this chart, DreamClear follows the requirements of the following recognized consensus standards for electrical and electromagnetic safety, as provided in the section titled "Declaration of Conformity to a Recognized Standard":

- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability;
- IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment; and
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD).

For these reasons, DreamClear is considered substantially equivalent to the Nomad predicate device.