October 11, 2023

DormoTech Medical Ltd.
% Paul Dryden
Consultant
ProMedic Consulting, LLC
131 Bay Point Dr. NE
Saint Petersburg, Florida 33704

Re: K230148
Trade/Device Name: Vlab
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, MNR
Dated: September 11, 2023
Received: September 11, 2023

Dear Paul Dryden:

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.

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,

Patrick Antkowiak -S

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 on last page.

510(k) Number *(if known)*

K230148

Device Name

DormoTech Vlab

Indications for Use *(Describe)*

The DormoTech Vlab 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 is intended for use on adults in a supervised (hospital) or unsupervised (home) environment.

Type of Use *(Select one or both, as applicable)*

☒ **XX** 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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Date Prepared:	11-Sep-2023
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Sponsor Contact:	Abed Nassir, Head of Firm
Submission Contact:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	DormoTech Vlab
Common/Usual Name:	Physiological Signal Amplifier
Classification Name:	Physiological Signal Amplifier
Product Code	GWL, MNR
Regulation Number	21 CFR 882.1835
Predicate Device:	Respironics, Alice PDx, K090484
Reference Device:	NOX, Nox Sleep System, K192469

Device Description:
The DormoTech Vlab 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 consists of:
The Head Unit
The head unit acquires electric signals indicative of EEG and eye movement located in the upper part of the unit (on the patient's forehead). Head relative position to body position are also measured using accelerometer sensors located in the upper part of the unit. The middle part of the unit is located below the nose and above the mouth, it contains 2 nasal (one in each nostril) and 1 oral airflow sensors, 1 EMG sensor, along with snoring sensor.

The Body Unit
The body unit is made of 2 belts, the upper belt sits on the chest, and the lower belt sits on the stomach of the patient. Both belts contain respiratory effort and accelerometer sensors, in addition, the upper belt contains an accelerometer to measure body position.

The Central Unit
Both the head and chest units communicate with the central units via Bluetooth, the wearable units send the measured data to the central unit. The central unit receives the data, it stores it within an internal Flash drive and then transmits the data via Wi-Fi to online servers for further diagnosis. Central unit, located in the test room (up to 10 meters from the patient). No contact with the patient.

Principle of Operation:
The device acquires and digitizes signals from sensors and sends them to a polysomnography system. Sensors are:

- Direct measurement of electrical potential at the skin (EEG, EMG, EOG).
- Thermistors (flow)
- Accelerometers (movement)
- Respiratory Effort
- Snoring Sensor

Indications for Use:
The DormoTech Vlab 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 is intended for use on adults in a supervised (hospital) or unsupervised (home) environment.

Patient Population:
Adults, 22 years and older

Substantial Equivalence:
The subject device, DormoTech Vlab, is substantially equivalent to the Respironics Alice PDx cleared under K090484 when compared to a cleared PSG system, the NOX Sleep system, K192496.

Performance Testing:

Non-clinical
Substantial equivalence to the predicate is based upon performance testing on collecting, recording and transferring data as well as the following.

- Biocompatibility
- Software Verification and Validation
- Electrical Safety
- Electromagnetic Compatibility Compliance
- Product Requirements Verification
- Consumables Verification

Clinical
We performed a prospective clinical study compared to a gold standard PSG study.

Summarizing the clinical study:
Study design:
An IEC approved, comparative, self-controlled, randomized, prospective study designed to assess the Vlab and compare its performance to a gold standard polysomnogram (PSG) conducted over 1 night in a sleep lab.

Study Locations:
Two sleep labs were used:

- Shamir Medical Center – Be'er Ya'akov, Israel
- Millenium Sleep Clinic – Be'er Sheva, Israel

Patient Population:

- Adults 22 years and older
- Male and female
- 47 subjects

The participants were patients who were referred by physicians for a full sleep study at the sleep laboratory.

Primary Endpoints Measures:

- AHI – Apnea-Hypopnea Index Score and Classification

Secondary Endpoints Measures:

- ODI – Oxygen Desaturation as measured by separate SpO2 sensor
- Snore-Total Snore %
- Sleep – Total Sleep Time (min), Sleep Efficiency (%), Sleep Stages [Wake, N1, N2, N3, REM] (%), Sleep Latency (min), Wake After Sleep Onset (min), REM Latency (min)
- Position: Supine position, Left, Right, Up [% from TST]

Table 9: Summary Table of Bland-Altman Plots for Compared Parameters

Parameter	Mean Difference (Lower CI, Upper CI)	Upper Limit of Agreement (Lower CI, Upper CI)	Lower Limit of Agreement (Lower CI, Upper CI)
AHI (events/h)	-0.1927 (-1.323, 0.9372)	6.823 (4.866, 8.78)	-7.209 (-9166, -5.252)
ODI (events/h)	-0.3244 (-1.108, 0.4597)	4.544 (3.186, 5.902)	-5.193 (-6.551, -3.835)
Snore (%)	1.085 (-0.525, 2.523)	10.01 (7.524, 12.5)	-7.843 (-10.33, -5.353
Sleep Latency (Minutes)	4.653 (-0.9411, 10.25)	38.01 (28.32, 47.7)	-28.7 (-38.39, -19.01)
REM Latency	-15.64 (-25.95, -5.327)	44.98 (27.12, 62.85)	-76.27 (-94.13, -58.4)
Wake after Sleep Onset (Minutes)	-4.300 (-10.53, 1.926)	31.77 (20.98, -42.55)	-40.37 (-51.15, -29.58)
REM (%)	0.4816 (-0.801, 1.764	8.129 (5.908, 10.35)	-7.166 (-9.388, -4.945)
N1 (%)	0.3263 (-1.839, 2.492)	13.24 (9.488, 16.99)	-12.59 (-16.34, -8.836)
N2 (%)	-2.484 (-5.084, 0.1152)	13.02 (8.513, 17.52)	-17.98 (-22.49, -13.48)
N3 (%)	1.011 (-0.07236, 2.093)	7.468 (5.592, 9.343)	-5.447 (-7.322, -3.571)
Wake (%)	0.1972 (-1.301, 1.696)	8.877 (6.282, 11.47)	-8.483 (-11.08, -5.887)
Total Sleep Time (Minutes)	0.72222 (-6.869, 8.313)	44.69 (31.55, 57.84)	-43.25 (-56.4, -30.1)
Sleep Efficiency (%)	-0.03333 (-1.536, 1.47)	8.673 (6.07, 11.28)	-8.74 (-11.34, -6.136)
Position (Up) (%)	0.01316 (-0.4649, 0.4913)	2.864 (2.036, 3.692)	-2.838 (-3.666, -2.01)
Position (Supine) (%)	0.9974 (-0.3433, 2.338)	8.991 (6.669, 11.31)	-6.997 (-9.319, -4.675)
Position (Left) (%)	0.3579 (-0.9967, 1.712)	8.435 (6.089, 10.78)	-7.719 (-10.07, -5.373)
Position (Right) (%)	-0.3974 (-1.61, 0.8149)	6.831 (4.732, 8.931)	-7.626 (-9.726, -5.526)

Conclusion:

The table above provides a comprehensive comparison between two devices across multiple sleep-related parameters. Most parameters show good agreement between the devices, as indicated by the mean difference values close to zero and narrow limits of agreement. This suggests that for many measures, such as AHi, ODI, and Snore, the devices are interchangeable. By considering both the statistical measures and the role of human scoring, this table offers a nuanced understanding of the performance and reliability of the Dormotech Vlab device when compared to the gold-standard PSG.

Table 1 – Comparison of Predicate

Features	**Subject Device** **DormoTech Vlab**	**Predicate** **Alice PDx - K090484**	**Comments**
Classification	GWL, MNR Physiological Signal Amplifier 882.1835	GWL, MNR, DQA Physiological Signal Amplifier 882.1835	
Indications for use	The DormoTech Vlab 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.	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.	Similar
Population	Adults	Adults	Similar
Environment of Use	Supervised (hospital) or unsupervised (home) environment	Supervised (hospital) or unsupervised (home) environment	Similar
Principle of Operation	Uses sensors to collect signals to be processed by cleared analysis software	Uses sensors to collect signals to be processed by cleared analysis software	Similar
Physiological signals collected	EEG, EOG, EMG, ECG Airflow Snore Thoracic and Abdominal Effort Body Position Requires separate SpO2 sensor and Heart (pulse) Rate from PPG	EEG, EOG, EMG, ECG Airflow Snore Thoracic and Abdominal Effort Body Position Requires separate SpO2 sensor and Heart (pulse) Rate from PPG	Similar
Device is	Wearable and portable	Wearable and portable	Similar
Prescriptive	Yes	Yes	Similar
Non-clinical Testing	**Respiratory Signals**		Bench testing was performed against the reference which confirmed the signal output. Then all measured parameters were compared in clinical study to NOX Sleep System - K192469
	Total Airflow		
	Snore		
	Respiratory Effort (Thoracic & Abdominal)		

Features	Subject Device DormoTech Vlab	Predicate Alice PDx - K090484	Comments
	EXG Signals		
	EEG		
	EOG		
	EMG		
	Position Signals		
	Body Position		
	Head Position		
	From recommended Nonin SpO2 sensor	From recommended Nonin SpO2 sensor	
Biocompatibility	Surface contact and Externally communicataing Limited duration < 24 hours	Surface contact and Externally communicataing Limited duration < 24 hours	Similar

Table 2 – Comparison to Reference

Features	**Subject Device** **DormoTech Vlab**	**Reference** **Nox Sleep System – K192469**	**Comments**
Classification	GWL, MNR Physiological Signal Amplifier 882.1835	OLZ, KZM Electroencephalograph 882.1400	This system includes more hardware than just sensors collecting data. It is considered a gold standard for comparative clinical studies.
Indications for use	The DormoTech Vlab 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 is intended for use on adults in a supervised (hospital) or unsupervised (home) environment.	The Nox Sleep System is used as an aid in the diagnosis of different sleep disorders and for the assessment of sleep. The Nox Sleep System is used to measure, record, display, organize, analyze, summarize, and retrieve physiological parameters during sleep and wake. The Nox Sleep System allows the user to decide on the complexity of the study by varying the number and types of physiological signals measured. The Nox Sleep System allows for generation of user/pre-defined reports based on subject´s data. The user of the Nox Sleep System are medical professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home.	The intended use of collecting data and the population and use environments are similar. The subject device does **not** analyze the signals.
Population	Adults, 22 years and older	Adults	Similar
Environment of Use	Supervised (hospital) or unsupervised (home) environment	Hospital) and home	Similar
Principle of Operation	Uses sensors to collect signals to be processed by cleared analysis software	Uses sensors to collect signals to be processed by cleared analysis software	Similar

Features	Subject Device DormoTech Vlab	Reference Nox Sleep System – K192469	Comments
Physiological signals collected	EEG, EOG, EMG, ECG Airflow Snore Thoracic and Abdominal Effort Body Position Pulse Rate (PPG) with a separate SpO2 sensor	EEG, EOG, EMG, ECG Airflow/Pressure Snore Thoracic and Abdominal Effort Body Position Pulse Rate (PPG) with a separate SpO2 sensor	The subject device includes sensors which are attached and the data collected and analyzed as part of a PSG sleep study.
Device is	Wearable and portable	Wearable and portable	Similar, yes the sensors for the reference are also wearable and portable.
Prescriptive	Yes	Yes	Similar
Performance Testing	**Respiratory Signals**	**Respiratory Signals**	In a comparative clinical study the results demonstrated that the Vlab was substantially equivalent in measuring the specified parameters.
	Total Airflow	**Total Airflow**	
	Snore	Snore	
	Respiratory Effort (Thoracic & Abdominal)	Respiratory Effort (Thoracic & Abdominal)	
	EXG Signals	**EXG Signals**	
	EEG	EEG	
	EOG	EOG	
	EMG	EMG	
	Position Signals	**Position Signals**	
	Body Position	Body Position	
	Head Position	Head Position	
	Plethysmography signal	**Plethysmography signal**	
	From recommended Nonin SpO2 sensor	From recommended Nonin SpO2 sensor	

Discussion of Differences:
The subject and predicate device are sensor arrays for use in collecting and transmitting data from sleep studies that is analyzed by automated, FDA-cleared software, which is not part of this submission.

The reference, NOX Sleep system, K192469, is a complete system that includes the sensors and software to analyze the collected data. It includes additional sensors and measured parameters which the subject device does not include, however, what is measured is similar to the predicate device.

We chose the reference as we needed to demonstrate that the signal acquisition quality for all parameters were substantially equivalent and in order to do that we had to process the collected signals through FDA-cleared analytic software for comparison.

The design of the sensor array is similar to both the predicate and reference as they are placed on the head and thoracic.

The technology of the sensors is similar to both the predicate and reference.

The differences do not raise different concerns or risk for safety or effectiveness when compared to both the predicate and reference.

Substantial Equivalence Discussion:
As presented in the tables above, the subject device is substantially equivalent to the predicate and the reference devices for indications for use, technological characteristics, environments of use, population and performance.

Conclusion:
The comparison of features, non-clinical and clinical testing support substantial equivalence to the predicate, Respironics Alice PDx, K090484.