January 8, 2025

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

Re: K242290
Trade/Device Name: DormoTech NLab
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, GWL, DQA
Dated: December 8, 2024
Received: December 9, 2024

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.

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,

FDA 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242290

Device Name

DormoTech Nlab

Indications for Use *(Describe)*

The DormoTech Nlab 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 patients greater than 6 years of age in a supervised (hospital) or unsupervised (home) environments.

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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Date Prepared:	8-Jan-25
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Sponsor Contact:	Abed Nassir, Head of Firm
Submission Contact:	Paul Dryden ProMedic Consulting LLC
Propriety or Trade Name:	DormoTech Nlab
Common/Usual Name:	Ventilatory Effort Recorder
Classification Name:	Ventilatory Effort Recorder
Primary Product Code:	MNR
Regulation Number:	21 CFR 868.2375
Secondary Product Code:	GWL, DQA
Reference Device:	NOX Medical, Nox T3, K082113 DormoTech, DormoTech Vlab, K230148
Predicate / Reference PPG sensor	Predicate: Dolphin Medical Inc, Dolphin ONE, K040380 Reference: Nellcor Puritan Bennett Inc., OxiMAX-FAST, K021089

Device Description:

The DormoTech Nlab 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 and is intended for use on patients greater than 6 years of age in a supervised (hospital) or unsupervised (home) environment.

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). Plethysmograph for Heart rate and SpO2 measurements, and 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 (thermistors), 1 EMG sensor, along with a 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 ExG Unit
The ExG unit is put on using an adhesive sticker on the leg/arm/chest (either leg/arm is ok). It consists of 3 electrodes that acquire leg/arm/chest ExG signal.

The Central Unit
The head, chest and ExG units communicate with the central unit via Bluetooth, the wearable units send

the measured data to the central unit. The central unit receives the data, stores it within an internal flash drive and then transmits the data via Wi-Fi to online servers for further diagnosis. The central unit is located in the test room (up to 10 meters from the patient). The central unit has no contact with the patient.

To ensure device reusability between sessions or patients, sections of the head unit have been designed to be detachable or with barriers between the sensor and patient's skin to stop direct contact. Specifically, the head unit incorporates (1) a detachable nasal and oral airflow section to allow for replacement of the section between each use of the device, (2) a removable barrier over the plethysmograph recorder to create a separation between the patient's skin and the recording device which is replaced between each use of the device and (3) a detachable textile on the inner side of the head unit (i.e., the side in direct contact with the patient's skin) to allow for replacement between each use of the device.

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)
- Plethysmograph (pulse rate and SpO2)
- Respiratory Effort
- Snoring Sensor

Indications for Use:
The DormoTech Nlab 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 patients greater than 6 years of age in a supervised (hospital) or unsupervised (home) environments.
Patient Population:
Patients greater than 6 years of age

Substantial Equivalence:
The subject device, DormoTech Nlab, is substantially equivalent to the Nox Medical, Nox T3 cleared under K082113.

The subject device's SpO2 sensor, Dormotech Nlab SpO2 sensor, is substantially equivalent to Dolphin Medical, Dolphin ONE, cleared under K040380.

Performance Testing:
Substantial equivalence to the predicate is based on performance testing.
We evaluated:

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

Clinical trial summary
Two (2) prospective clinical studies were performed. The first for the added population of pediatrics over

the age of 6 compared to a gold standard PSG study and the second for validation of the SpO2 sensor in accordance with ISO 14155 and ISO 80601-2-61.

The first clinical study involving overnight PSG recordings included a total of 26 patients (50% female), with an average age of 11 years and average BMI of 26. The trial involved simultaneous monitoring of physiological sleep signals via recordings by the subject and predicate devices. Analyses demonstrated no significant differences in primary or secondary sleep endpoint measures between the subject and predicate devices.

The second clinical study involving clinical validation of the SpO2 sensor included a total of 12 patients (33% female) with an average age of 33 years and included subgroup analyses for race and ethnicity. The study involved recording of SpO2 using the subject device and simultaneous monitoring of arterial HbO2 saturations at six different levels of oxyhemoglobin saturation between 70-100%. The Root Mean Square Error (RMSE) between the two measurements of 2.53% suggests that the measurement method being evaluated is within the expected range of accuracy. Furthermore, subgroup analyses were performed according to skin pigmentation and sex and revealed no systematic differences across these parameters. According to skin pigmentation, RMSE was 3.18%, 2.53%, 1.57% for light, medium and dark skin pigmentation, respectively. Moreover, subgroup analyses revealed no systematic differences across sex with RMSE values at 2.64% and 2.18% for male and female sex, respectively.

Summarizing the clinical study results:

Clinical Trials for Pediatrics Over the Age of 6:

Study design:
An IEC approved, comparative, self-controlled, randomized, prospective study designed to assess the Nlab 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:
• Children 6 years and older
• Male and female (50% female)
• 26 subjects were recruited, not all enrolled subjects completed the study. 24 out of 26 subjects completed the test and filled out both questionnaires and were considered for demographics, safety, and usability analysis.

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]

Parameter	Mean Difference (Lower CI, Upper CI)	Upper Limit of Agreement (Lower CI, Upper CI)	Lower Limit of Agreement (Lower CI, Upper CI)
AHI	0.2875	4.05	-3.475
(events/h)	[-0.5231,1.098]	[2.646,5.454]	[-4.879, -2.071]
ODI	-0.1042	2.358	-2.566
(events/h)	[-0.6346,0.4262]	[1.439,3.276]	[-3.485, -1.647]
Snore	1.995	11.79	-7.801
(%)	[-0.2207,4.212]	[7.954,15.63]	[-11.64, -3.963]
Sleep Latency	0.9727	15.05	-13.1
(Minutes)	[-2.211,4.156]	[9.531,20.56]	[-18.61, -7.586]
REM Latency	-0.2864	12.74	-18.46
(Minutes)	[-6.393,0.6654]	[6.624,18.85]	[-24.58, -12.35]
Wake after Sleep Onset	-2.091	12.45	-16.63
(Minutes)	[-5.381, -1.199]	[6.754,18.15]	[-22.33, -10.94]
REM	0.6045	8.552	-7.343
(%)	[-1.193,2.402]	[5.438,11.67]	[-10.46, -4.229]
N1	-1.659	8.151	-11.47
(%)	[-3.878,0.5602]	[4.308,12]	[-15.31, -7.626]
N2	-1.095	7.8	-9.991
(%)	[-3.108, -0.9169]	[4.315,11.29]	[-13.48, -6.506]
N3	2.173	9.58	-5.235
(%)	[0.497,3.848]	[6.678,12.48]	[-8.137, -2.332]
Wake	-1.127	4.97	-7.224
(%)	[-2.506,0.2519]	[2.581,7.358]	[-9.613, -4.835]
Total Sleep Time	4.00	44.23	-36.23
(Minutes)	[-5.1,13.1]	[28.47,59.99]	[-51.99, -20.47]
Sleep Efficiency	-0.1773	6.988	-7.342
(%)	[-1.798,1.444]	[4.18,9.795]	[-10.15, -4.535]
Position (Up)	-0.2792	2.107	-2.665
(%)	[-0.7932,0.2348]	[1.216,2.997]	[-3.555, -1.775]
Position (Supine)	1.892	10.06	-6.278
(%)	[0.1316,3.652]	[7.013,13.11]	[-9.326, -3.229]
Position (Left)	0.725	6.716	-5.266
(%)	[-0.5657,2.016]	[4.48,8.951]	[-7.501, -3.03]
Position (Right)	-0.3042	7.91	-8.518
(%)	[-2.074,1.465]	[4.845,10.97]	[-11.58, -5.453]

Conclusion:

The table above provides a comprehensive comparison between the 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, the performance of the Dormotech Nlab device when compared to the gold-standard PSG is substantially equivalent.

Clinical Trials for SpO2 sensor:

A study is to determine the accuracy of the DormoTech Nlab SpO2 sensor in accordance with the FDA Guidance on Pulse Oximeters – Premarket Notification Submissions [510(k)s], in the range of arterial HbO2 saturations from 100% to 70% was conducted.

In the analysis, 259 data points from 12 subjects were included. The subjects represent a diverse group in terms of age, height, weight, ethnicity, and skin types, which is beneficial for generalizing findings across different demographics. Subjects span all six types, indicating a wide range of skin types from very fair (Type I) to deeply pigmented dark (Type VI). A Root Mean Square Error (RMSE) of 2.53% for this range suggests that the model or measurement method being evaluated is fairly accurate. Subgroup analyses were performed according to skin pigmentation and sex and revealed no systematic differences across these parameters. According to skin pigmentation, RMSE was 3.18%, 2.53%, 1.57% for light, medium, dark skin pigmentation, respectively. Moreover, subgroup analyses revealed no systematic differences across sex with RMSE values at 2.64% and 2.18% for male and female sex, respectively. Additionally, the narrow 95% confidence interval for the mean bias further highlights the precision and reliability of the bias estimate.

Features	**Subject Device** **DormoTech Nlab**	**Predicate** **Nox T3 (K082113)**	**Comments**
Classification	MNR Physiological Signal Amplifier 882.1835	MNR Physiological Signal Amplifier 882.1835	Similar
Indications for use	The DormoTech Nlab 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 patients greater than 6 years of age in a supervised (hospital) or unsupervised (home) environments.	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 (Noxturnal). The Nox T3 system is indicated for use in patients greater than 2 years of age. The Nox T3 system is NOT intended for any patient monitoring or automatic diagnosis. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including patient's home. The Nox T3 system is used for patients suspected of suffering from Sleep Disordered Breathing (SDB) or Periodic Limb Movement Disorder (PLMD).	The Indications for Use for the proposed DormoTech Nlab device are identical to those of the predicate device with the exception that use for patients age 6 and older is not excluded in the subject DormoTech Nlab labelling. Bench testing of the proposed DormoTech Nlab was conducted to demonstrate substantial equivalence to the predicate device. The proposed device has the same intended use and employs the same fundamental scientific technology.
Population	Patients greater than 6 years of age.	Patients greater than 2 years of age.	Subject device was not verified in patients under 6 years old.
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 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**		In a comparative clinical study the results demonstrated that the Nlab was substantially equivalent in measuring the specified parameters. The study results can be seen in the previous submission for DormoTech Vlab cleared under K230148. For the SpO2 sensor, DormoTech conducted a clinical validation study
	Total Airflow	**Total Airflow**	
	Snore	Snore	
	Respiratory Effort (Thoracic and Abdomen)	Respiratory Effort (Thoracic and Abdomen)	
	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**	
	DormoTech Nlab SpO2 sensor	From Nonin SpO2 sensor	

Features	**Subject Device DormoTech Nlab**	**Reference DormoTech Vlab (K230148)**	**Comments**
Classification	GWL, MNR Physiological Signal Amplifier 882.1835	GWL, MNR Physiological Signal Amplifier 882.1835	Similar
Indications for use	The DormoTech Nlab 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 patients greater than 6 years of age in a supervised (hospital) or unsupervised (home) environments.	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 Indications for Use for the proposed DormoTech Nlab device are identical to those of the reference device with the exception that use for pediatrics age 6 and older is not excluded in the subject DormoTech Nlab labeling. Bench testing of the proposed DormoTech Nlab was conducted to demonstrate substantial equivalence to the predicate device. The proposed device has the same intended use and employs the same fundamental scientific technology.
Population	Patients greater than 6 years of age.	Adults	
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 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	Added SpO2 sensor, the SpO2 has been tested in accordance with ISO 14155 and ISO 80601-2-61.

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.
	Total Airflow	**Total Airflow**	
	Snore	Snore	
	Respiratory Effort (Thoracic and Abdomen)	Respiratory Effort (Thoracic and Abdomen)	
	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**	
	DormoTech Nlab SpO2 sensor	From Nonin SpO2 sensor	
Biocompatibility	Surface contact and Externally communicating Limited duration < 24 hours	Surface contact and Externally communicating Limited duration < 24 hours	Similar

Features	**Subject Device** **DormoTech Nlab SpO2 sensor**	**Predicate** Dolphin Medical, Dolphin ONE, K040380	**Reference** Nellcor OxiMAX MAX-FAST, K021089	**Comments**
Indications for use	The DormoTech Nlab SpO2 sensor is indicated for use in continuous monitoring of arterial oxygen saturation and pulse rate.	The Dolphin ONE Oximetry Sensors are indicated for use in continuous monitoring of arterial oxygen saturation and pulse rate	The Nellcor OxiMAX adhesive forehead reflectance sensor, model MAX-FAST, is indicated for single-patient use when continuous noninvasive arterial oxygen saturation and pulse rate monitoring are required for adult or pediatric (≥10 kg) patients.	Similar
Population	Patients greater than 6 years old	Adults and pediatrics weighing > 30 Kg	Adults and pediatrics weighing > 10 Kg	Similar to reference
Environment of Use	Supervised (hospital) or unsupervised (home) environment	Supervised (hospital) or unsupervised (home) environment	Supervised (hospital) or unsupervised (home) environment	Similar
Principle of Operation	Pulse oximetry is governed by the principles of a) Oxyhemoglobin (oxygenated blood) and b) deoxyhemoglobin (non-\ oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.	Pulse oximetry is governed by the principles of a) Oxyhemoglobin (oxygenated blood) and b) deoxyhemoglobin (non-\ oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.	Pulse oximetry is governed by the principles of a) Oxyhemoglobin (oxygenated blood) and b) deoxyhemoglobin (non-\ oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry). The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.	Similar
Type of use	Reusable	Reusable	Single use	Similar to predicate
Reprocess protocol	Disposable adhesive sticker is put on forehead SpO2 enclosure	Disposable adhesive disc and headband	NA	Similar to predicate – both have their skin-contacting parts as disposable
Measurement Site	Forehead	Forehead	Forehead	Similar
Prescriptive	Yes	Yes	Yes	Similar
Sterility	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile	Similar
Accuracy, A_{RMS}				
SpO2	70-100%±2.53%	70-100%±2%	70-100%±2%	Device is not meant to be used in emergency or life threatening situations. Device is intended to be used in sleep disorder screenings with low risk to users. ISO 80601-2-61 allows for Arms of up to 4%
Pulse rate	20-250±3 bpm	Did not include in submission	20-250±3 bpm	Similar to reference
Biocompatibility	ISO-10993 compliant	ISO-10993 compliant	ISO-10993 compliant	Similar

Discussion of Differences:
The subject and predicate devices are sensor arrays for use in collecting and transmitting data from sleep studies that is analyzed by automated, FDA-cleared software.

The Indications for Use for the proposed Dormotech Nlab device are identical to those of the predicate device with the exception that use for pediatrics age 6 and older, as the device was not validated on pediatrics aged 2-6 years old

Bench testing of the proposed Dormotech Nlab was conducted to demonstrate substantial equivalence to the predicate device.

The DormoTech Nlab acquires and records a SpO2 signal from a plethysmograph (PPG) sensor, while predicate device Nox T3, K082113 uses a separate PPG sensor. To validate DormoTech Nlab sensor, Dormotech conducted a clinical validation study in accordance with ISO 14155 and ISO 80601-2-61. The reference, DormoTech Medical LTD, DormoTech Vlab, K230148 uses the same technology and design as subject device, DormoTech Nlab. DormoTech Nlab adds a leg/arm/chest ExG and a SpO2 signal, that were not present in the reference device. Bench testing and clinical validation were conducted on the Nlab device to ensure safety and accuracy.

The design of the sensor array is similar to both the predicate and reference as they are placed on the head, thoracic and leg/arm/chest. The technology of the sensors is the same as 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, Nox T3, cleared under K082113, and the reference device, Dormotech Vlab, Cleared under K230148, for indications for use, technological characteristics, environments of use, population and performance. The subject device's SpO2 sensor, Dormotech Nlab SpO2 sensor, to its predicate and reference devices, Dolphin Medical, Dolphin ONE and Nellcor OxiMAX MAX-FAST, cleared under K040380 and K021089, respectfully.

Conclusion:
The comparison of features and performance testing support substantial equivalence to the predicate, Nox Medical Inc. Nox T3, K082113, and for its SpO2 sensor, Dormotech Nlab SpO2 sensor showed equivalence to the reference device, Dolphin Medical, Dolphin ONE, K040380.