March 14, 2025

Nox Medical ehf
% Hrishikesh Gadagkar
Senior Principal
Rqm+
2790 Mosside Blvd #800
Monroeville, Pennsylvania 15146

Re: K241960
Trade/Device Name: DeepRESP
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: July 3, 2024
Received: July 3, 2024

Dear Hrishikesh Gadagkar:

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)*
K241960

Device Name
DeepRESP

Indications for Use *(Describe)*
DeepRESP is an aid in the diagnosis of various sleep disorders where subjects are often evaluated during the initiation or follow-up of treatment of various sleep disorders. The recordings to be analyzed by DeepRESP can be performed in a hospital, patient home, or an ambulatory setting. It is indicated for use with adults (22 years and above) in a clinical environment by or on the order of a medical professional.

DeepRESP is intended to mark sleep study signals to aid in the identification of events and annotation of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); infer sleep staging with arousals with EEG and in the absence of EEG. All output is subject to verification by a medical professional.

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
March 13, 2025

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DEVICE INFORMATION
Proprietary Name/Trade Name: DeepRESP

Common Name:	Electroencephalograph, Automatic Event Detection Software for Polysomnograph with Electroencephalograph
Regulation Number:	882.1400
Class:	II
Product Code:	OLZ
Premarket Review:	Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices (DHT5A), Office of Neurological and Physical Medicine Devices (OHT5)
Review Panel:	Neurology

PREDICATE DEVICE IDENTIFICATION

The DeepRESP is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Additional Predicate*
K192469	Nox Sleep System / Nox Medical	x	
K202142	Sleepware G3 / Respironics Inc		x

DEVICE DESCRIPTION

DeepRESP is a cloud-based software as a medical device (SaMD), designed to perform analysis of sleep study recordings, with and without EEG signals, providing data for the assessment and diagnosis of sleep-related disorders. Its algorithmic framework provides the derivation of sleep staging including arousals, scoring of respiratory events and key parameters such as the Apnea-Hypopnea Index (AHI).

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DeepRESP is hosted on a serverless stack. It consists of:

- A web Application Programming Interface (API) intended to interface with a third-party client application, allowing medical professionals to access DeepRESP's analytical capabilities.
- Predefined sequences called Protocols that run data analyses, including artificial intelligence and rule-based models for the scoring of sleep studies, and a parameter calculation service.
- A Result storage using an object storage service to temporarily store outputs from the DeepRESP Protocols.

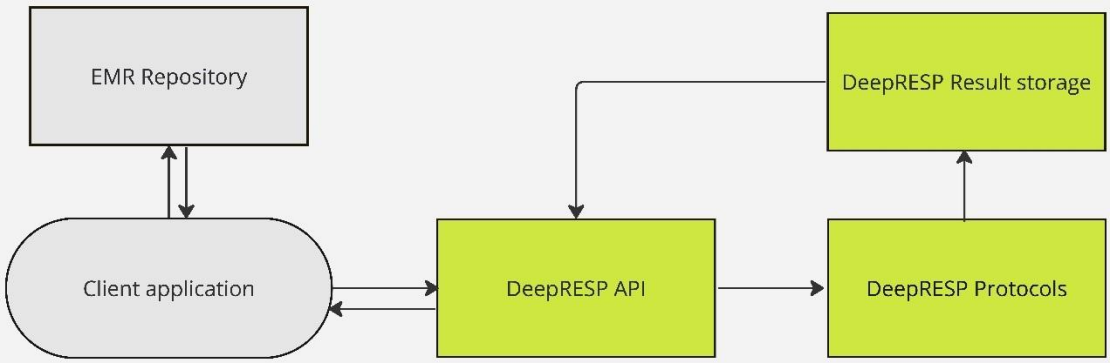

Figure 1 – DeepRESP dataflow

INDICATIONS FOR USE

DeepRESP is an aid in the diagnosis of various sleep disorders where subjects are often evaluated during the initiation or follow-up of treatment of various sleep disorders. The recordings to be analyzed by DeepRESP can be performed in a hospital, patient home, or an ambulatory setting. It is indicated for use with adults (22 years and above) in a clinical environment by or on the order of a medical professional.

DeepRESP is intended to mark sleep study signals to aid in the identification of events and annotation of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); infer sleep staging with arousals with EEG and in the absence of EEG. All output is subject to verification by a medical professional.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Nox Medical believes that the DeepRESP is substantially equivalent to the primary predicate device based on the information summarized here:

Trade/Device Name	Subject Device: DeepRESP	Primary Predicate Device: Nox Sleep System	Additional Predicate Device: Sleepware G3
Manufacturer	Nox Medical	Nox Medical	Respironics, Inc.
510(k) Number	K241960	K192469	K202142
Regulation Number	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.1400
Regulation Name	Electroencephalograph	Electroencephalograph	Electroencephalograph
Regulatory Class	Class II	Class II	Class II
Product Code(s)	OLZ	Primary: OLZ Subsequent: KZM	OLZ
Intended Use	DeepRESP is a cloud-based artificial intelligence-enabled software application used for analysis (automatic scoring), retrieval, and summarization of data recorded with sleep monitoring devices. The device uses an algorithm to categorize sleep-related events that help aid in the diagnosis of sleep-related disorders. The results of the analyzed data are then transferred to another software for manual scoring, display and reporting	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 the patient's home.	Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation, and networking of data received from monitoring devices used to categorize sleep related events that help aid in the diagnosis of sleep-related disorders. The optional Somnolyzer software application is intended to mark sleep study signals in order to aid in the identification of events and annotation of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); and infer sleep staging in the absence of EEG. All output subject to verification by a qualified user.
Indications for Use	DeepRESP is an aid in the diagnosis of various sleep disorders where subjects are often evaluated during the initiation or follow-up of treatment of various sleep disorders. The recordings to be	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,	Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation, and networking of data received from monitoring devices

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	analyzed by DeepRESP can be performed in a hospital, patient home, or an ambulatory setting. It is indicated for use with adults (22 years and above) in a clinical environment by or on the order of a medical professional. DeepRESP is intended to mark sleep study signals to aid in the identification of events and annotation of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); infer sleep staging with arousals with EEG and in the absence of EEG. All output is subject to verification by a medical professional.	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 the patient's home.	used to categorize sleep related events that help aid in the diagnosis of sleep-related disorders. It is indicated for use with adults (18 and older) and infant patients (one year old or less) in a clinical environment by or on the order of a physician. The optional Somnolyzer scoring algorithms are for use with adults (18 and older) to generate an output that is ready for review and interpretation by a physician. Cardio-Respiratory Sleep Staging (CReSS) is an additional functionality of Somnolyzer which uses standard Home Sleep Apnea Test HSAT signals (in the absence of EEG signals) to infer sleep stage.
Use Environment	Physician office. No limitation on where data are acquired.	Physician office. No limitation on where data are acquired.	Physician office. No limitation on where data are acquired.
Patient Population	22 years and older	22 years and older	18 years and older
Type of Use	Prescription Use only	Prescription Use only	Prescription Use only
Signals analyzed	EEG, Chin EMG, EOG, Abdomen and Thorax RIP, SpO2, Nasal Pressure, Body position	EEG, Chin EMG, EOG Abdomen and Thorax RIP, SpO2; Cannula flow; Body position	EEG, ECG, EOG, EMG waveforms; SpO2; respiratory effort; airflow; heart/pulse rate; snoring loudness; body movement and position.
Sleep Scoring with EEG	Automatic ready for review by medical professional Manual through a 3rd party application.	Automatic Manual	Automatic ready for review and interpretation by a physician Manual
Sleep Scoring Without EEG	Automatic ready for review by medical professional	Not available	Automatic ready for review and interpretation by a physician
Score Sleep Disorder Respiratory Events	Automatic ready for review by medical professional Manual through a 3rd party application.	Automatic Manual	Automatic ready for review and interpretation by a physician Manual
Score Arousal Events with EEG	Automatic ready for review by medical professional Manual through a 3rd party application.	Manual	Automatic ready for review and interpretation by a physician Manual

Score Arousal Events without EEG	Automatic ready for review by medical professional	Not available	Automatic ready for review and interpretation by a physician
Score Body Position	Automatic ready for review by medical professional Manual through a 3rd party application.	Automatic Manual	Automatic ready for review and interpretation by a physician Manual
Manual Review of Automatic Scoring	Yes	Yes	Yes
Sleep Study Reporting	Yes	Yes	Yes
Hardware Components	Not included	Included	Not included
Physical Characteristics	API-based software operates in the cloud.	Operates on any PC with Windows 10.	Operates on Windows 10 PC, and Microsoft Surface Pro (for offline review).
Performance Testing	IEC 62304:2006/ A1:2015 ISO 14971:2019 ANSI/AAMI SW96:2023	IEC 62304:2006 ISO 14971:2007	IEC 62304:2006/ A1:2015 ISO 14971:2007
Clinical performance Type I/II studies	**Severity classification** AHI ≥ 5 PPA% [95% CI]: 87.5 NPA% [95% CI]: 91.9 OPA% [95% CI]: 87.9 AHI ≥ 15 PPA% [95% CI]: 74.1 NPA% [95% CI]: 94.7 OPA% [95% CI]: 81.5	**Severity classification** AHI ≥ 5 PPA% [95% CI]: 73.6 NPA% [95% CI]: 65.8 OPA% [95% CI]: 73.0 AHI ≥ 15 PPA% [95% CI]: 54.5 NPA% [95% CI]: 89.8 OPA% [95% CI]: 67.2	N/A
	Sleep stages Wake PPA% [95% CI]: 95.4 NPA% [95% CI]: 94.6 OPA% [95% CI]: 94.8 REM	**Sleep stages** Wake PPA% [95% CI]: 56.7 NPA% [95% CI]: 98.1 OPA% [95% CI]: 89.8 REM	N/A

	PPA% [95% CI]: 84.3 NPA% [95% CI]: 98.3 OPA% [95% CI]: 96.3 N1 PPA% [95% CI]: 42.8 NPA% [95% CI]: 89.7 OPA% [95% CI]: 87.1 N2 PPA% [95% CI]: 74.2 NPA% [95% CI]: 82.8 OPA% [95% CI]: 78.7 N3 PPA% [95% CI]: 43.1 NPA% [95% CI]: 98.5 OPA% [95% CI]: 91.6	PPA% [95% CI]: 74.8 NPA% [95% CI]: 95.1 OPA% [95% CI]: 92.1 N1 PPA% [95% CI]: 9.2 NPA% [95% CI]: 98.2 OPA% [95% CI]: 93.3 N2 PPA% [95% CI]: 80.3 NPA% [95% CI]: 73.4 OPA% [95% CI]: 76.7 N3 PPA% [95% CI]: 82.4 NPA% [95% CI]: 91.7 OPA% [95% CI]: 90.5	
	Respiratory events PPA% [95% CI]: 72.0 NPA% [95% CI]: 94.2 OPA% [95% CI]: 87.2	**Respiratory events** PPA% [95% CI]: 58.5 NPA% [95% CI]: 95.4 OPA% [95% CI]: 81.7	N/A
	Arousal events ArI ICC [95% CI]: 0.63	N/A	**Arousal events** ArI ICC [95% CI]: 0.794
Clinical performance Type III studies	**Severity classification** AHI ≥ 5 PPA% [95% CI]: 93.1 NPA% [95% CI]: 81.1 OPA% [95% CI]: 92.5 AHI ≥ 15 PPA% [95% CI]: 82.1	**Severity classification** AHI ≥ 5 PPA% [95% CI]: 82.4 NPA% [95% CI]: 56.6 OPA% [95% CI]: 81.1 AHI ≥ 15 PPA% [95% CI]: 60.4	N/A

	NPA% [95% CI]: 92.3 OPA% [95% CI]: 84.7	NPA% [95% CI]: 89.3 OPA% [95% CI]: 67.9	
	Sleep states Wake PPA% [95% CI]: 76.2 NPA% [95% CI]: 96.8 OPA% [95% CI]: 92.7 NREM PPA% [95% CI]: 94.5 NPA% [95% CI]: 79.0 OPA% [95% CI]: 89.2 REM PPA% [95% CI]: 79.1 NPA% [95% CI]: 98.1 OPA% [95% CI]: 95.4	**Sleep states** Wake PPA% [95% CI]: 56.8 NPA% [95% CI]: 98.0 OPA% [95% CI]: 89.9 NREM PPA% [95% CI]: 93.8 NPA% [95% CI]: 70.0 OPA% [95% CI]: 85.7 REM PPA% [95% CI]: 74.7 NPA% [95% CI]: 95.1 OPA% [95% CI]: 92.2	N/A
	Respiratory events PPA% [95% CI]: 75.4 NPA% [95% CI]: 87.8 OPA% [95% CI]: 83.7	**Respiratory events** PPA% [95% CI]: 58.5 NPA% [95% CI]: 95.4 OPA% [95% CI]: 81.7	N/A
	Arousal events ArI ICC [95% CI]: 0.76	N/A	**Arousal events** ArI ICC [95% CI]: 0.73

SUMMARY OF NON-CLINICAL TESTING

Software verification and validation testing were performed per IEC 62304:2006/A1:2015 *Medical device software – Software life cycle processes*, IEC 82304-1:2017 *Health Software – general requirements for product safety* and the FDA guidance *General Principles of Software Validation* to demonstrate safety and performance based on current industry standards and that we met the intended use and user needs. Relative documentation was prepared as recommended in FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

SUMMARY OF CLINICAL TESTING

The clinical performance of DeepRESP was validated by a retrospective study. It used manually scored sleep recordings, originating from sleep clinics in the United States, performed as part of routine clinical work matching indicated use of the study device and patient population.

The performance of DeepRESP with regards to scoring of sleep recordings with electroencephalography (EEG) (i.e. Type I and II), and sleep recordings without EEG (i.e. Type III) was validated. Two separate studies were conducted, one to validate DeepRESP with scoring of Type I-II recordings and a second one with scoring of Type III recordings. The studies were done by evaluating the agreement in scoring and clinical indices resulting from the automatic scoring by DeepRESP compared to manual scoring. The performance of DeepRESP was compared to the agreement of the automatic scoring of the predicate device to manual scoring. The same collection of sleep recordings and same manual scoring were used when comparing the automatic scoring of DeepRESP and the predicate device. The study method was a retrospective data study comparing paired differences.

In both studies DeepRESPs performance with regards to sleep state estimation and respiratory event scoring was validated against the Nox Sleep System (K192469). For evaluation for performance of arousal scoring, Sleepware G3 (K202142) was used as a comparator.

For validating scoring performance for Type I recordings, a total of 2,224 Type I recordings were used. For validating scoring performance for Type III recordings, a total of 3,488 sleep recordings were used, including 2,213 Type I recordings and 1,275 Type II recordings. The Type I and II recordings were processed as Type III recordings by utilizing only the subset of signals from them that are common to Type III recordings.

The recording collection used for validation of Type I scoring consisted of 46% Females, had individuals in all age groups (22-35, 36-45, 46-55, 56-65, 65+), and all BMI groups (<25, 25-30, <30). The recording collection used for validation of Type III scoring consisted of 33% females, had individuals in all age groups (22-35, 36-45, 46-55, 56-65, 65+), and all BMI groups (<25, 25-30, <30). The Type I and II sleep recordings were collected as part of standard clinical care for patients suspected of suffering from sleep disorders. The patients came from urban, suburban, and rural areas with a high-level of race/ethnicity diversity (Caucasian or White, Black or African American, Other, Not Reported). The patient population was therefore considered as representative of patients seeking medical services for sleep disorders in the United States.

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Results:

In the retrospective study intended to validate DeepRESP for Type I recordings:

- In comparison to the primary predicate device with regards to severity classification of sleep recordings, with AHI ≥5 and AHI ≥15 as severity thresholds, the study device showcased non-inferiority against the primary predicate device. Additionally, for OPA (overall percentage agreement) and PPA (positive percentage agreement) the study device achieved superiority for AHI ≥15 and AHI ≥5.
- In comparison to the primary predicate device with regards to overall respiratory event scoring the study device showcased non-inferiority for all endpoints, additionally achieving superiority for OPA.
- In comparison to the primary predicate device with regards to sleep state estimation the study device showcased non-inferiority for PPA, NPA, and OPA.
- In comparison to the additional predicate device with regards to arousal event scoring, the study device achieved non-inferiority.

The performance agreement of DeepRESP for type I studies compared to manual scoring can be seen in table 1.

Table 1. Performance agreement of DeepRESP compared to manual soring. Scoring of Type I recordings.

	PPA% [95% CI]	NPA % [95% CI]	OPA % [95% CI]
AHI ≥5	87.5 [86.2, 89.0]	91.9 [87.4, 95.8]	87.9 [86.6, 89.3]
AHI ≥15	74.1 [72.0, 76.5]	94.7 [93.2, 96.2]	81.5 [79.9, 83.3]
AHI ≥30	66.8 [63.6, 70.1]	97.9 [97.2, 98.6]	86.7 [85.3, 88.0]
Respiratory events	72.0 [70.9, 73.2]	94.2 [94.0, 94.5]	87.2 [86.8, 87.5]
Wake	95.4 [95.1, 95.6]	94.6 [94.4, 94.9]	94.8 [94.6, 95.0]
NREM	92.3 [92.0, 92.6]	92.7 [92.4, 92.9]	92.4 [92.2, 92.6]
N1	42.8 [41.6, 43.8]	89.7 [89.3, 90.1]	87.1 [86.7, 87.5]
N2	74.2 [73.4, 74.9]	82.8 [82.3, 83.3]	78.7 [78.3, 79.1]
N3	43.1 [41.4, 44.8]	98.5 [98.4, 98.7]	91.6 [91.3, 91.9]
REM	84.3 [83.6, 85.0]	98.3 [98.2, 98.4]	96.3 [96.2, 96.4]
Arousal events	62.2 [61.2, 63.1]	89.3 [88.8, 89.7]	81.4 [81.1, 81.7]

In the retrospective study intended to validate DeepRESP for Type III recordings:

- In comparison to the primary predicate device with regards to severity classification of sleep recordings, with AHI ≥5 and AHI ≥15 as severity thresholds, the study device showcased superiority for PPA for all thresholds. In the case of NPA, and OPA, the study device showcased non-inferiority compared to the primary predicate device.
- In comparison to the primary predicate device with regards to overall respiratory event scoring the study device showcased non-inferiority for NPA, achieving superiority for OPA and PPA.
- In comparison to the primary predicate device with regards to sleep state estimation the study device showcased non-inferiority for PPA, NPA, and OPA.

- In comparison to the additional predicate device with regards to arousal event scoring, the study device achieved non-inferiority.

The performance agreement of DeepRESP for Type III studies compared to manual scoring can be seen in table 2.

Table 2. Performance agreement for DeepRESP compared to manual scoring. Scoring of Type III recordings.

	PPA% [95% CI]	NPA % [95% CI]	OPA % [95% CI]
AHI ≥5	93.1 [92.2, 93.9]	81.1 [75.1, 86.6]	92.5 [91.7, 93.3]
AHI ≥15	82.1 [80.6, 83.5]	92.3 [90.5, 94.0]	84.7 [83.5, 85.8]
AHI ≥30	75.9 [73.7, 78.0]	96.8 [96.0, 97.6]	87.2 [86.2, 88.4]
Respiratory events	75.4 [74.6, 76.1]	87.8 [87.4, 88.1]	83.7 [83.4, 84.0]
Wake	76.2 [75.5, 77.0]	96.8 [96.6, 97.0]	92.7 [92.5, 92.9]
NREM	94.5 [94.2, 94.7]	79.0 [78.4, 79.6]	89.2 [88.9, 89.4]
REM	79.1 [78.2, 79.9]	98.1 [98.0, 98.2]	95.4 [95.2, 95.5]
Arousal events	66.8 [65.8, 67.6]	86.8 [86.4, 87.1]	81.8 [81.5, 82.0]

The validation results demonstrate that the predefined clinical performance criteria of DeepRESP against the primary predicate device and additional predicate device have been met for studies with and without EEG signals. DeepRESP is therefore considered as deemed effective in its intended purpose, i.e. categorising sleep related events, that help aid in the diagnosis of sleep related disorders.

CONCLUSION

Based on the verification and validation testing performed in accordance with IEC 62304:2006/A1:2015, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the primary predicate device. The DeepRESP device is demonstrated to be substantially equivalent to the primary predicate device.