



November 17, 2025

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

Re: K252330
Trade/Device Name: DeepRESP
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: August 15, 2025
Received: August 19, 2025

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,

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

Indications for Use

510(k) Number (if known)

K252330

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, a patient's home, or an ambulatory setting. It is indicated for use with adults (18 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 annotations of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DATE PREPARED

November 13, 2025

MANUFACTURER AND 510(k) OWNER

Nox Medical ehf

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Email: hgadagkar@rqmplus.com

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 (subject device) is substantially equivalent to the following predicate:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>	<i>Additional Predicate</i>
K241960	DeepRESP / Nox Medical	x	
K192469	Nox Sleep System / Nox Medical		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) and Central Apnea-Hypopnea Index (CAHI).

DeepRESP (K252330) 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.

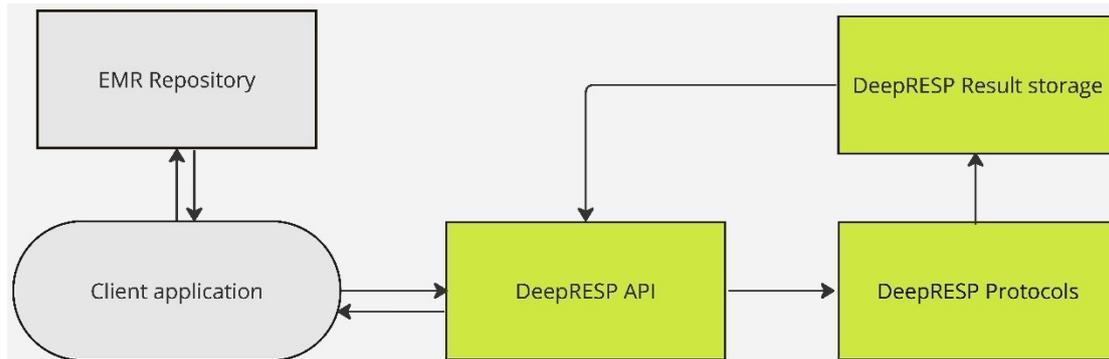


Figure 1 – DeepRESP dataflow

The following constitute changes in DeepRESP (K252330) in comparison with DeepRESP (K241960) device:

- a) Patient population extended to include patients 18 of age and above.
- b) Automated Central Sleep Apnea (CSA) scoring.
- c) Respiratory and Sleep staging model update to improve performance.

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, a patient's home, or an ambulatory setting. It is indicated for use with adults (18 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 annotations of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); and 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 (K252330) is substantially equivalent to the predicate devices listed below, based on the information summarized here:

Trade/Device Name	Subject Device	Primary Predicate Device: DeepRESP	Additional Predicate Device: Nox Sleep System
Manufacturer	Nox Medical	Nox Medical	Nox Medical
510(k) Number	K252330	K241960	K192469
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	OLZ	Primary: OLZ Subsequent: KZM
Intended Use	<p>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</p>	<p>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</p>	<p>The Nox Sleep System is used as an aid in the diagnosis of different sleep disorders and for the assessment of sleep.</p> <p>The Nox Sleep System is used to measure, record, display, organize, analyze, summarize, and retrieve physiological parameters during sleep and wake.</p> <p>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.</p> <p>The Nox Sleep System allows for generation of user/pre-defined reports based on subject's data.</p> <p>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.</p> <p>The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.</p>
Indications for Use	<p>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, a patient's home, or an ambulatory setting. It is indicated for use with adults (18 years and above) in a clinical environment by</p>	<p>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</p>	<p>The Nox Sleep System is used as an aid in the diagnosis of different sleep disorders and for the assessment of sleep.</p> <p>The Nox Sleep System is used to measure, record, display, organize, analyze, summarize, and retrieve physiological parameters during sleep and wake.</p> <p>The Nox Sleep System allows the user to decide on the complexity of the study by</p>

	<p>or on the order of a medical professional.</p> <p>DeepRESP is intended to mark sleep study signals to aid in the identification of events and annotations of traces; automatically calculate measures obtained from recorded signals (e.g., magnitude, time, frequency, and statistical measures of marked events); and infer sleep staging with arousals with EEG and in the absence of EEG. All output is subject to verification by a medical professional.</p>	<p>the order of a medical professional.</p> <p>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.</p>	<p>varying the number and types of physiological signals measured.</p> <p>The Nox Sleep System allows for generation of user/pre-defined reports based on subject's data.</p> <p>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.</p> <p>The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.</p>
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	18 years and older	22 years and older	22 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 (Cannula flow), Body position	EEG, Chin EMG, EOG, Abdomen and Thorax RIP, SpO2, Nasal Pressure (Cannula flow), Body position	EEG, Chin EMG, EOG Abdomen and Thorax RIP, SpO2; Nasal pressure (Cannula flow); Body position
Sleep Scoring with EEG	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic ready for review and interpretation by a physician. Manual
Sleep Scoring Without EEG	Automatic ready for review by medical professional	Automatic ready for review by medical professional	Not available
Score Sleep Disorder Respiratory Events	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic Manual
Score Arousal Events with EEG	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic ready for review by medical professional Manual through a 3 rd party application.	Manual
Score Arousal Events without EEG	Automatic ready for review by medical professional	Automatic ready for review by medical professional	Not available
Score Central Sleep Apneas and Obstructive Sleep Apneas	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 3 rd party application.	Automatic ready for review by medical professional Manual through a 3 rd party application.	Automatic Manual
Manual Review of Automatic Scoring	Yes	Yes	Yes
Sleep Study Reporting	Yes	Yes	Yes

Hardware Components	Not included	Not included	Included
Physical Characteristics	API-based software operates in the cloud.	API-based software operates in the cloud.	Operates on any PC with Windows 10.
Performance Testing	IEC 62304:2006/ A1:2015 ISO 14971:2019 ANSI/AAMI SW96:2023	IEC 62304:2006/ A1:2015 ISO 14971:2019 ANSI/AAMI SW96:2023	IEC 62304:2006 ISO 14971:2007

Clinical Performance

Trade/ Device Name	Subject Device: DeepRESP v2.0	Primary Predicate Device: DeepRESP v1.0 (K241960)	Additional Predicate Device: Nox Sleep System (K192469)	Observed paired differences (Δ PPA, Δ NPA, Δ OPA) between subject device and predicate devices. Bootstrapped 95% CI
Clinical performance Type I/II studies	Severity classification AHI \geq 5 PPA%: 87.7 NPA%: 76.5 OPA%: 87.3	Severity classification AHI \geq 5 PPA%: 87.5 NPA%: 91.9 OPA%: 87.9	Severity classification AHI \geq 5 Not used in comparison.	Severity classification AHI \geq 5 Δ PPA%: -4.7 [-5.6, -3.9] Δ NPA%: 27.0 [19.2, 35.3] Δ OPA%: -3.5 [-4.4, -2.6]
	AHI \geq 15 PPA%: 71.9 NPA%: 94.8 OPA%: 78.2	AHI \geq 15 PPA%: 74.1 NPA%: 94.7 OPA%: 81.5	AHI \geq 15 Not used in comparison.	AHI \geq 15 Δ PPA%: -3.2 [-4.3, -2.1] Δ NPA%: 4.9 [3.3, 6.7] Δ OPA%: -1.0 [-1.9, -0.1]
	CAHI \geq 5 PPA%: 80.0 NPA%: 98.0 OPA%: 97.2	CAHI \geq 5 N/A	CAHI \geq 5 Not reported in K192469. Non-inferiority is demonstrated in next column.	Nox Sleep System (K192469) CAHI \geq 5 Δ PPA%: 26.6 [18.4, 34.6] Δ NPA%: -1.0 [-1.5, -0.5] Δ OPA%: 0.3 [-0.3, 1.0]
	Sleep stages Wake PPA%: 92.8 NPA%: 95.8 OPA%: 95.1	Sleep stages Wake PPA%: 95.4 NPA%: 94.6 OPA%: 94.8	Sleep stages Wake Not used in comparison.	Sleep stages Wake Δ PPA%: -2.8 [-3.0, -2.6] Δ NPA%: 1.5 [1.4, 1.7] Δ OPA%: 0.6 [0.5, 0.7]
	REM PPA%: 82.5 NPA%: 98.8 OPA%: 96.5	REM PPA%: 84.3 NPA%: 98.3 OPA%: 96.3	REM Not used in comparison.	REM Δ PPA%: -2.4 [-2.7, -2.1] Δ NPA%: 0.3 [0.2, 0.3] Δ OPA%: -0.1 [-0.2, -0.1]
	NREM1 PPA%: 43.1 NPA%: 94.5 OPA%: 91.7	NREM1 PPA%: 42.8 NPA%: 89.7 OPA%: 87.1	NREM1 Not used in comparison.	NREM1 Δ PPA%: 1.7 [1.0, 2.3] Δ NPA%: 4.6 [4.4, 4.9] Δ OPA%: 4.5 [4.3, 4.7]
	NREM2 PPA%: 78.1 NPA%: 91.5 OPA%: 85.3	NREM2 PPA%: 74.2 NPA%: 82.8 OPA%: 78.7	NREM2 Not used in comparison.	NREM2 Δ PPA%: 4.4 [3.9, 5.0] Δ NPA%: 8.0 [7.7, 8.3] Δ OPA%: 6.4 [6.1, 6.6]
	NREM3 PPA%: 87.5 NPA%: 94.6 OPA%: 93.7	NREM3 PPA%: 43.1 NPA%: 98.5 OPA%: 91.6	NREM3 Not used in comparison.	NREM3 Δ PPA%: 45.6 [44.4, 46.8] Δ NPA%: -4.0 [-4.1, -3.8] Δ OPA%: 2.0 [1.8, 2.2]
	Respiratory events PPA%: 71.2 NPA%: 93.2	Respiratory events PPA%: 72.0 NPA%: 94.2	Respiratory events Not used in comparison.	Respiratory events DeepRESP (K241960) Δ PPA%: -1.0 [-1.3, -0.6] Δ NPA%: 2.3 [2.1, 2.5]

	<p>OPA%: 85.6</p> <p>All apnea PPA%: 83.7 NPA%: 98.2 OPA%: 97.1</p> <p>Central apnea PPA%: 79.3 NPA%: 99.2 OPA%: 99.0</p> <p>Obstructive apnea PPA%: 76.2 NPA%: 98.4 OPA%: 97.0</p> <p>Hypopnea PPA%: 60.1 NPA%: 92.9 OPA%: 83.5</p> <p>Desaturation PPA%: 98.5 NPA%: 95.5 OPA%: 96.1</p> <p>Arousal events PPA%: 62.1 NPA%: 89.1 OPA%: 81.5</p>	<p>OPA%: 87.2</p> <p>All apnea PPA%: 85.1 NPA%: 97.7 OPA%: 96.7</p> <p>Central apnea N/A</p> <p>Obstructive apnea N/A</p> <p>Hypopnea PPA%: 59.6 NPA%: 94.2 OPA%: 85.4</p> <p>Desaturation PPA%: 96.4 NPA%: 99.6 OPA%: 98.9</p> <p>Arousal events PPA%: 62.2 NPA%: 89.3 OPA%: 81.4</p>	<p>All apnea Not used in comparison.</p> <p>Central apnea PPA, NPA, and OPA not reported in K192469. Non-inferiority is demonstrated in next column</p> <p>Obstructive apnea PPA, NPA, and OPA not reported in K192469. Non-inferiority is demonstrated in next column</p> <p>Hypopnea Not used in comparison.</p> <p>Desaturation Not used in comparison.</p> <p>Arousal events N/A</p>	<p>ΔOPA%: 1.2 [1.0, 1.3]</p> <p>All apnea (Bootstrapped paired median differences) DeepRESP (K241960) ΔPPA%: 0.0 [-0.7, 0.8] ΔNPA%: 0.9 [0.8, 1.0] ΔOPA%: 0.8 [0.7, 0.9]</p> <p>Central apnea Nox Sleep System (K192469) ΔPPA%: 21.4 [16.2, 27.0] ΔNPA%: -0.4 [-0.5, -0.4] ΔOPA%: -0.2 [-0.3, -0.2]</p> <p>Obstructive apnea (Bootstrapped paired median differences) Nox Sleep System (K192469) ΔPPA%: 9.8 [7.6, 11.9] ΔNPA%: -0.5 [-0.6, -0.4] ΔOPA%: 0.2 [0.0, 0.3]</p> <p>Hypopnea (Bootstrapped paired median differences) DeepRESP (K241960) ΔPPA%: -0.2 [-0.7, 0.2] ΔNPA%: 2.0 [1.8, 2.2] ΔOPA%: 1.3 [1.2, 1.5]</p> <p>Desaturation (Bootstrapped paired median differences) DeepRESP (K241960) ΔPPA%: 0.5 [0.5, 0.6] ΔNPA%: -0.9 [-0.9, -0.9] ΔOPA%: -0.6 [-0.6, -0.6]</p> <p>Arousal events DeepRESP (K241960) ΔPPA%: -0.8 [-0.8, -0.7] ΔNPA%: 0.2 [0.2, 0.2] ΔOPA%: -0.1 [-0.1, -0.1]</p>
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Trade/ Device Name	Subject Device: DeepRESP v2.0	Primary Predicate Device: DeepRESP v1.0 (K241960)	Additional Predicate Device: Nox Sleep System (K192469)	Observed paired differences (Δ PPA, Δ NPA, Δ OPA) between subject device and predicate devices. Bootstrapped 95% CI
Clinical performance	Severity classification	Severity classification	Severity classification	Severity classification DeepRESP (K241960)
Type III studies	AHI \geq 5 PPA%: 91.0 NPA%: 78.0 OPA%: 90.6	AHI \geq 5 PPA%: 93.1 NPA%: 81.1 OPA%: 92.5	AHI \geq 5 Not used in comparison	AHI \geq 5 Δ PPA%: -4.1 [-4.7, -3.5] Δ NPA%: 33.9 [26.7, 42.0] Δ OPA%: -3.0 [-3.6, -2.3]
HSAT-Flow	AHI \geq 15 PPA%: 78.1 NPA%: 93.9 OPA%: 81.7	AHI \geq 15 PPA%: 82.1 NPA%: 92.3 OPA%: 84.7	AHI \geq 15 Not used in comparison	AHI \geq 15 Δ PPA%: -3.6 [-4.5, -2.8] Δ NPA%: 6.7 [5.1, 8.3] Δ OPA%: -1.2 [-1.9, -0.4]

	<p>CAHI \geq 5 PPA%: 80.7 NPA%: 98.0 OPA%: 97.2</p> <p><u>Sleep states</u></p> <p>Wake PPA%: 79.7 NPA%: 96.6 OPA%: 92.9</p> <p>REM PPA%: 77.0 NPA%: 98.1 OPA%: 95.2</p> <p>NREM PPA%: 94.2 NPA%: 80.1 OPA%: 89.1</p> <p><u>Respiratory events</u> PPA%: 74.4 NPA%: 92.0 OPA%: 85.5</p> <p><u>All apnea</u> PPA%: 84.5 NPA%: 98.2 OPA%: 97.0</p> <p><u>Central apnea</u> PPA%: 77.5 NPA%: 99.2 OPA%: 99.0</p> <p><u>Obstructive apnea</u> PPA%: 78.4 NPA%: 98.4 OPA%: 97.0</p> <p><u>Hypopnea</u> PPA%: 63.9 NPA%: 91.7 OPA%: 83.3</p> <p><u>Desaturation</u> PPA%: 98.8 NPA%: 96.3 OPA%: 96.9</p>	<p>CAHI \geq 5 N/A</p> <p><u>Sleep states</u></p> <p>Wake PPA%: 76.2 NPA%: 96.8 OPA%: 92.7</p> <p>REM PPA%: 79.1 NPA%: 98.1 OPA%: 95.4</p> <p>NREM PPA%: 94.5 NPA%: 79.0 OPA%: 89.2</p> <p><u>Respiratory events</u> PPA%: 75.4 NPA%: 87.8 OPA%: 83.7</p> <p><u>All apnea</u> PPA%: 84.9 NPA%: 96.7 OPA%: 95.8</p> <p><u>Central apnea</u> N/A</p> <p><u>Obstructive apnea</u> N/A</p> <p><u>Hypopnea</u> PPA%: 64.0 NPA%: 89.1 OPA%: 82.6</p> <p><u>Desaturation</u> PPA%: 96.9 NPA%: 99.5 OPA%: 98.8</p>	<p>CAHI \geq 5 Not reported in K192469. Non-inferiority is demonstrated in next column</p> <p><u>Sleep states</u></p> <p>Wake Not used in comparison.</p> <p>REM Not used in comparison.</p> <p>NREM Not used in comparison.</p> <p><u>Respiratory events</u> Not used in comparison.</p> <p><u>All apnea</u> Not used in comparison.</p> <p><u>Central apnea</u> PPA, NPA, and OPA not reported in K192469. Non-inferiority is demonstrated in next column</p> <p><u>Obstructive apnea</u> PPA, NPA, and OPA not reported in K192469. Non-inferiority is demonstrated in next column</p> <p><u>Hypopnea</u> Not used in comparison.</p> <p><u>Desaturation</u> Not used in comparison.</p>	<p>Nox Sleep System (K192469) CAHI \geq 5 ΔPPA%: 24.3 [17.0, 31.0] ΔNPA%: -0.6 [-1.0, -0.2] ΔOPA%: 0.5 [-0.1, 1.0]</p> <p><u>Sleep states</u> DeepRESP (K241960)</p> <p>Wake ΔPPA%: 2.3 [2.1, 2.4] ΔNPA%: 0.6 [0.6, 0.7] ΔOPA%: 1.0 [1.0, 1.0]</p> <p>REM ΔPPA%: 0.4 [0.3, 0.5] ΔNPA%: 0.1 [0.1, 0.1] ΔOPA%: 0.1 [0.1, 0.2]</p> <p>NREM ΔPPA%: 0.7 [0.7, 0.7] ΔNPA%: 1.2 [1.1, 1.3] ΔOPA%: 0.9 [0.8, 0.9]</p> <p><u>Respiratory events</u> DeepRESP (K241960) ΔPPA%: -0.5 [-0.8, -0.3] ΔNPA%: 2.7 [2.5, 2.8] ΔOPA%: 1.5 [1.4, 1.6]</p> <p><u>All apnea (Bootstrapped paired median differences)</u> DeepRESP (K241960) ΔPPA%: 0.0 [-0.5, 0.5] ΔNPA%: 1.0 [0.9, 1.1] ΔOPA%: 0.9 [0.8, 1.0]</p> <p><u>Central apnea</u> Nox Sleep System (K192469) ΔPPA%: 15.2 [11.4, 19.1] ΔNPA%: -0.4 [-0.5, -0.4] ΔOPA%: -0.3 [-0.3, -0.3]</p> <p><u>Obstructive apnea (Bootstrapped paired median differences)</u> Nox Sleep System (K192469) ΔPPA%: 2.4 [1.1, 3.7] ΔNPA%: -0.0 [-0.1, 0.1] ΔOPA%: 0.2 [0.1, 0.3]</p> <p><u>Hypopnea (Bootstrapped paired median differences)</u> DeepRESP (K241960) ΔPPA%: 0.3 [0.0, 0.6] ΔNPA%: 2.3 [2.2, 2.4] ΔOPA%: 1.7 [1.6, 1.8]</p> <p><u>Desaturation (Bootstrapped paired median differences)</u> DeepRESP (K241960) ΔPPA%: 0.6 [0.6, 0.6] ΔNPA%: -1.0 [-1.0, -0.9] ΔOPA%: -0.6 [-0.6, -0.5]</p>
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	Arousal events PPA%: 64.0 NPA%: 90.5 OPA%: 83.1	Arousal events PPA%: 66.8 NPA%: 86.8 OPA%: 81.8	Arousal events N/A	Arousal events DeepRESP (K241960) ΔPPA%: -0.8 [-0.9, -0.8] ΔNPA%: 0.5 [0.5, 0.5] ΔOPA%: 0.1 [0.1, 0.2]
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Trade/ Device Name	Subject Device: DeepRESP v2.0	Primary Predicate Device: DeepRESP v1.0 (K241960)	Additional Predicate Device: Nox Sleep System (K192469)	Observed paired differences (ΔPPA, ΔNPA, ΔOPA) between subject device and predicate devices. Bootstrapped 95% CI
Clinical performance Type III studies HSAT-RIP	Severity classification AHI ≥ 5 PPA%: 93.7 NPA%: 63.5 OPA%: 92.8	Severity classification AHI ≥ 5 PPA%: 93.1 NPA%: 81.1 OPA%: 92.5	Severity classification AHI ≥ 5 Not used in comparison	Severity classification AHI ≥ 5 ΔPPA%: -1.4 [-1.9, -0.8] ΔNPA%: 19.3 [12.0, 26.9] ΔOPA%: -0.8 [-1.4, -0.2]
	AHI ≥ 15 PPA%: 81.0 NPA%: 91.1 OPA%: 83.4	AHI ≥ 15 PPA%: 82.1 NPA%: 92.3 OPA%: 84.7	AHI ≥ 15 Not used in comparison	AHI ≥ 15 ΔPPA%: -0.6 [-1.5, 0.3] ΔNPA%: 3.9 [2.3, 5.6] ΔOPA%: 0.5 [-0.3, 1.2]
	CAHI ≥ 5 PPA%: 79.5 NPA%: 97.6 OPA%: 96.9	CAHI ≥ 5 N/A	CAHI ≥ 5 Not reported in K192469. Non-inferiority is demonstrated in next column	Nox Sleep System (K192469) CAHI ≥ 5 ΔPPA%: 23.0 [15.3, 31.1] ΔNPA%: -0.9 [-1.3, -0.5] ΔOPA%: 0.1 [-0.4, 0.6]
	Sleep states Wake PPA%: 79.7 NPA%: 96.6 OPA%: 92.9	Sleep states Wake PPA%: 76.2 NPA%: 96.8 OPA%: 92.7	Sleep states Wake Not used in comparison.	Sleep states DeepRESP (K241960) Wake ΔPPA%: 2.3 [2.1, 2.4] ΔNPA%: 0.6 [0.6, 0.7] ΔOPA%: 1.0 [1.0, 1.0]
	REM PPA%: 77.0 NPA%: 98.1 OPA%: 95.2	REM PPA%: 79.1 NPA%: 98.1 OPA%: 95.4	REM Not used in comparison.	REM ΔPPA%: 0.4 [0.3, 0.5] ΔNPA%: 0.1 [0.1, 0.1] ΔOPA%: 0.1 [0.1, 0.1]
	NREM PPA%: 94.2 NPA%: 80.1 OPA%: 89.1	NREM PPA%: 94.5 NPA%: 79.0 OPA%: 89.2	NREM Not used in comparison.	NREM ΔPPA%: 0.7 [0.7, 0.7] ΔNPA%: 1.2 [1.1, 1.3] ΔOPA%: 0.9 [0.8, 0.9]
	Respiratory events PPA%: 75.0 NPA%: 90.7 OPA%: 84.8	Respiratory events PPA%: 75.4 NPA%: 87.8 OPA%: 83.7	Respiratory events Not used in comparison.	Respiratory events DeepRESP (K241960) ΔPPA%: 0.0 [-0.2, 0.3] ΔNPA%: 1.4 [1.2, 1.5] ΔOPA%: 0.9 [0.8, 1.0]
	All apnea PPA%: 81.1 NPA%: 95.7 OPA%: 94.5	All apnea PPA%: 84.9 NPA%: 96.7 OPA%: 95.8	All apnea Not used in comparison.	All apnea (Bootstrapped paired median differences) DeepRESP (K241960) ΔPPA%: -3.3 [-4.3, -2.5] ΔNPA%: -1.5 [-1.7, -1.3] ΔOPA%: -1.6 [-1.8, -1.5]
	Central apnea PPA%: 78.8 NPA%: 99.2 OPA%: 99.0	Central apnea N/A	Central apnea PPA, NPA, and OPA not reported in K192469.	Central apnea Nox Sleep System (K192469) ΔPPA%: 16.6 [12.9, 20.2] ΔNPA%: -0.5 [-0.5, -0.5] ΔOPA%: -0.3 [-0.4, -0.3]

	<p><u>Obstructive apnea</u> PPA%: 74.3 NPA%: 96.0 OPA%: 94.4</p> <p><u>Hypopnea</u> PPA%: 58.9 NPA%: 90.7 OPA%: 81.0</p> <p><u>Desaturation</u> PPA%: 98.8 NPA%: 96.3 OPA%: 96.9</p> <p><u>Arousal events</u> PPA%: 64.0 NPA%: 90.5 OPA%: 83.0</p>	<p><u>Obstructive apnea</u> N/A</p> <p><u>Hypopnea</u> PPA%: 64.0 NPA%: 89.1 OPA%: 82.6</p> <p><u>Desaturation</u> PPA%: 96.9 NPA%: 99.5 OPA%: 98.8</p> <p><u>Arousal events</u> PPA%: 66.8 NPA%: 86.8 OPA%: 81.8</p>	<p>Non-inferiority is demonstrated in next column</p> <p><u>Obstructive apnea</u> PPA, NPA, and OPA not reported in K192469. Non-inferiority is demonstrated in next column</p> <p><u>Hypopnea</u> Not used in comparison.</p> <p><u>Desaturation</u> Not used in comparison.</p> <p><u>Arousal events</u> N/A</p>	<p><u>Obstructive apnea (Bootstrapped paired median differences) Nox Sleep System (K192469)</u> ΔPPA%: -1.7 [-3.4, -0.2] ΔNPA%: -2.5 [-2.6, -2.3] ΔOPA%: -2.4 [-2.6, -2.2]</p> <p><u>Hypopnea (Bootstrapped paired median differences) DeepRESP (K241960)</u> ΔPPA%: -4.7 [-5.1, -4.2] ΔNPA%: 1.2 [1.1, 1.4] ΔOPA%: -0.6 [-0.7, -0.4]</p> <p><u>Desaturation (Bootstrapped paired median differences) DeepRESP (K241960)</u> ΔPPA%: 0.6 [0.6, 0.6] ΔNPA%: -1.0 [-1.0, -0.9] ΔOPA%: -0.6 [-0.6, -0.5]</p> <p><u>Arousal events DeepRESP (K241960)</u> ΔPPA%: -0.8 [-0.9, -0.8] ΔNPA%: 0.5 [0.5, 0.5] ΔOPA%: 0.1 [0.1, 0.2]</p>
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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*. Nox Medical demonstrated safety and effectiveness based on current industry standards. All documentation was prepared as recommended in the FDA Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

SUMMARY OF CLINICAL TESTING

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

The performance of DeepRESP with regard to scoring 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 Type I-II recordings and a second one with scoring Type III recordings. The performance of DeepRESP on Type III recordings was validated in two configurations: one where thorax and abdomen RIP, nasal pressure, and SpO2 are available (HSAT-Flow), the second where thorax and abdomen RIP and SpO2 are available (HSAT-RIP). 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 between the automatic scoring of the predicate device and manual scoring. The same collection of sleep recordings and the 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, the subject device DeepRESP's performance was validated against the primary predicate DeepRESP (K241960). To evaluate the performance scoring of central sleep apnea (CSA) and obstructive sleep apnea (OSA), Nox Sleep System (K192469) was used as a comparator.

To assess the performance of the subject device DeepRESP for use in patients aged 18 years and older, an evaluation of the performance of the primary endpoints was validated in the subgroup aged between 18 and 21 years old compared to the other sub-groups ages. The performance of classifying sleep recordings was validated for $AHI \geq 5$, $AHI \geq 15$, and $CAHI \geq 5$. The PPA, NPA, and OPA for these classifications were evaluated for this age group as well as age groups of older patients. Further analysis was done by plotting histograms of the AHI and CAHI values of the patients in each age group, and plotting histograms of the AHI and CAHI values of the misclassified sleep recordings in each age group. This analysis demonstrated that misclassifications occurred most frequently for AHI and CAHI values close to the decision boundary. This behavior was consistent across all age groups. Therefore, it was concluded that the patient's age did not impact the performance of the subject device.

For validating scoring performance for Type I/II PSG recordings, a total of 4,030 PSG recordings were used. For validating scoring performance for Type III recordings, a total of 5,771 sleep recordings were used, including 4,037 Type I recordings and 1,734 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/II scoring consisted of 44% Females, had individuals in all age groups (18-21, 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 35% females, had individuals in all age groups (18-21, 22-35, 36-45, 46-55, 56-65, >65), and all BMI groups (<25, 25-30, >30). 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). The patient population was therefore considered representative of patients seeking medical services for sleep disorders in the United States. Medical professionals should assess whether DeepRESP's outputs are reliable for rare disease presentations, as such cases may be underrepresented in their training and validation data.

CONCLUSION

Based on the verification and validation testing performed in accordance with IEC 62304:2006/A1:2015, it can be concluded that DeepRESP (K252330) does not raise new issues of safety or effectiveness compared to the primary predicate device. The subject device DeepRESP has been demonstrated to be substantially equivalent to the predicate devices.