March 20, 2026

Nox Medical Ehf
% Hrishikesh Gadagkar
Regulatory Consultant
Rqm+
5000 Centregreen Way, Suite 100
Cary, North Carolina 27513

Re: K260585
Trade/Device Name: Noxturnal Web
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV
Dated: February 20, 2026
Received: February 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	

Please provide the device trade name(s).

Noxturnal Web

Please provide your Indications for Use below.

Noxturnal Web is intended to be used for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults (18 years and above).

Noxturnal Web is a software-only medical device to be used to analyze physiological signals and manually score sleep study results, including the staging of sleep, AHI, and detection of sleep disordered breathing events including obstructive apneas.

It is intended to be used under the supervision of a clinician in a clinical environment.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) Summary

DATE PREPARED
February 20, 2026

MANUFACTURER AND 510(k) OWNER
Nox Medical ehf
Katrinartuni 2,
IS - 105 Reykjavik,
Iceland
Telephone: +354 570 7170
Official Contact: Elísabet Finnbogadóttir, Director, Regulatory Affairs

REPRESENTATIVE/CONSULTANT
Hrishikesh Gadagkar,
Sr. Principal, RQM+
2790 Mosside Blvd #800, Monroeville, PA
Telephone: +1 (410) 245-0501
Email: hgadagkar@rqmplus.com

DEVICE INFORMATION

Device Proprietary Name/Trade Name:	Noxturnal Web
Device Classification Name:	Standard Polysomnograph with Electroencephalograph
Regulation Number:	21 CFR 882.1400
Classification:	Class II
Classification Product Code:	OLV
510k Review Panel:	Neurology

PREDICATE DEVICE IDENTIFICATION

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate device*	*Reference device*
K241288	Noxturnal Web / Nox Medical	x	
K201054	SOMNOscreen plus / Somnomedics GmbH		x

DEVICE DESCRIPTION

Noxturnal Web is a web-based software that can be utilized to screen various sleep and respiratory-related sleep disorders. The users of Noxturnal Web are medical professionals who have received training in the areas of hospital/clinical procedures, physiological monitoring of human subjects, or sleep disorder investigation. Users can input a sleep study recording stored on the cloud (electronic medical record repository) using their established credentials. Once the sleep study data has been retrieved, the Noxturnal Web software can be used to display, manually analyze, generate reports and print the pre-recorded physiological signals.

Noxturnal Web is used to read sleep study data for the display, analysis, summarization, and retrieval of physiological parameters recorded during sleep and awake. Noxturnal Web facilitates a user to review or manually score a sleep study either before the initiation of treatment or during the treatment follow-up for various sleep and respiratory-related sleep disorders.

Noxturnal Web presents information from the input sleep study data in an organized layout. Multiple visualization layouts (e.g., Study Overview, Respiratory Signal Sheet, etc.) are available to allow the users to optimize the visualization of key data components. The reports generated by Noxturnal Web allow the inclusion of custom user comments, and these reports can then be viewed on the screen and/or printed.

INTENDED USE

Noxturnal Web is indicated for use in the displaying, analysis and printing of pre-recorded biophysical parameters acquired during sleep for the purpose of assisting in the diagnosis of sleep and respiratory-related sleep disorders.

Noxturnal Web is intended to be used as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults (18 years and above).

INDICATIONS FOR USE

Noxturnal Web is intended to be used for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults (18 years and above).

Noxturnal Web is a software-only medical device to be used to analyze physiological signals and manually score sleep study results, including the staging of sleep, AHI, and detection of sleep disordered breathing events including obstructive apneas.

It is intended to be used under the supervision of a clinician in a clinical environment.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Nox Medical believes that the Noxturnal Web v2.0 is substantially equivalent to the predicate device Noxturnal Web v1.0 (K241288) and to the reference device SOMNOscreen plus (K201054) based on the information summarized here:

Trade/Device Name	**Subject Device: Noxturnal Web v2.0**	**Predicate Device: Noxturnal Web v1.0 (K241288)**	**Reference Device: SOMNOscreen plus (K201054)**
Manufacturer	Nox Medical	Nox Medical	Somnomedics GmbH
510(k) Number	TBD	K241288	K201054
Regulation Description	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)	OLV	OLV	Main: OLV; Sub: MNR
Intended Use	Noxturnal Web is indicated for use in the	Noxturnal Web is indicated for use in the	The SOMNOscreen® plus is indicated for use in the

	displaying, analysis and printing of pre-recorded biophysical parameters acquired during sleep for the purpose of assisting in the diagnosis of sleep and respiratory-related sleep disorders. Noxturnal Web is intended to be used as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults (18 years and above).	displaying, analysis and printing of pre-recorded biophysical parameters acquired during sleep for the purpose of assisting in the diagnosis of sleep and respiratory-related sleep disorders. Noxturnal Web is intended to be used as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only.	recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders. The device is a non-life-supporting physiological signal recording device intended to be used for studies testing adults and children/adolescents suspected of having sleep-related breathing disorders. This device is NOT designed to be used in a Life Support situation. This device is not designed for use on patients with cardiac pacemakers.
Indications for Use	Noxturnal Web is intended to be used for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults (18 years and above). Noxturnal Web is a software-only medical device to be used to analyze physiological signals and manually score sleep study results, including the staging of sleep, AHI, and detection of sleep disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment.	Noxturnal Web is intended to be used for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. Noxturnal Web is a software-only medical device to be used to analyze physiological signals and manually score sleep study results, including the staging of sleep, AHI, and detection of sleep disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment.	The SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children (age 2 to 12 years)/adolescents (age 12 and above) suspected of having sleep-related breathing disorders.
Environment of Use	Clinical Environment	Clinical Environment	Clinical Environment
Target Users	Medical Professionals	Medical Professionals	Medical Professionals
Target Patient Population	Adults (18 years and above)	Adults only	General Population (adults and children/adolescents)
Type of Use	Prescription Use only	Prescription Use only	Prescription Use only
Aid/Assist in the diagnosis of sleep and respiratory-related sleep disorders	Yes	Yes	Yes
Arousal Scoring	Yes	Yes	Yes
Respiratory Events Scoring	Yes	Yes	Yes
Leg Movement Events Scoring	Yes	Yes	Yes
Sleep Study Scoring Method	Manual	Manual	Manual
Sleep Stage Scoring (Stage W, Stages N1/N2/N3, Stage R)	Yes	Yes	Yes
Report Generation	Yes	Yes	Yes

Calculation of AASM standardized indices	Yes	Yes	Yes
EEG	Yes	Yes	Yes
EOG	Yes	Yes	Yes
EMG	Yes	Yes	Yes
ECG	Yes	Yes	Yes
Chest/Abdomen movements / Respiratory Effort	Yes	Yes	Yes
Airflow	Yes	Yes	Yes
Oxygen Saturation	Yes	Yes	Yes
Body Position / Activity	Yes	Yes	Yes
Hardware Components	Not included	Not included	Included
Software Type	Web-based	Web-based	Computer program
Physical Characteristics	Web-based software operating in the cloud with Windows or Mac OS	Web-based software operating in the cloud with Windows or Mac OS	MS Windows-based application
Performance Testing	• IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION • ANSI AAMI ISO 14971:2019 • ANSI AAMI SW96:2023 • IEC 82304-1 Edition 1.0 2016-10 • ISO 20417 First edition 2021-04 Corrected version 2021-12 • ISO IEC 29147 First edition 2014-02-15 • AAMI TIR57:2016 • ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	• IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION • ANSI AAMI ISO 14971:2019 • ANSI AAMI SW96:2023 • IEC 82304-1 Edition 1.0 2016-10 • ISO 20417 First edition 2021-04 Corrected version 2021-12 • ISO IEC 29147 First edition 2014-02-15 • AAMI TIR57:2016 ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text)	• IEC/ANSI 60601-1:2005 • EN 60601-1-2:2015 • IEC 62366-1:2015
Standard of Scoring Manual	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events

SUMMARY OF NON-CLINICAL TESTING

The FDA-recognized standards were applied throughout the design process of Noxturnal Web. Verification and Validation testing of all requirement specifications defined for Noxturnal Web was conducted and passed according to the device's intended use to ensure product safety, effectiveness, and reliability.

Software verification and validation testing was performed per IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software – Software life cycle processes to demonstrate safety and performance based on current industry standards.

SUMMARY OF CLINICAL TESTING

Clinical data were not relied upon for a determination of substantial equivalence.

CONCLUSION

Noxturnal Web v2.0, the subject device, is Software as a Medical Device (SaMD) designed for diagnostic evaluation by physicians to aid in diagnosing sleep and respiratory-related sleep disorders by manually analysing various physiological signals to derive actionable clinical insights from pre-recorded data acquired during sleep. Noxturnal Web v2.0 is intended for use in patients of 18 years and above.

Noxturnal Web v1.0 (K241288) was identified as a predicate device because they share same intended use and same technological characteristics with the subject device, Noxturnal Web v2.0.

The subject device, the predicate device (K241288) and the reference device (K201054) are intended to aid/assist in the diagnosis of sleep and sleep-related breathing disorders. The subject device Noxturnal Web v2.0 is an evolution of the initial cleared version of same device Noxturnal Web v1.0 (K241288). The functionalities and technical characteristics between the subject device Noxturnal Web v2.0 and the predicate device Noxturnal Web v1.0 (K241288) are the same. Similar to the reference device, the subject device includes sleep recordings review and analysis from patients aged 18 to 21 years old, which are based on the manual scoring rules defined by AASM for adult patients. This difference with the predicate device does not present new or modified risks, and therefore, they do not raise different questions of safety and effectiveness.

The difference in technological characteristics and in patient population between the subject device, the predicate device and the reference device have been addressed through software verification/validation testing and performance testing. The results of the software and performance testing validate that Noxturnal Web v2.0 meets its requirements, performs as intended, and is as safe and effective as the predicate device.

Based upon the results of the comparison of intended use and indications for use, software verification and validation, performance testing and cybersecurity guidance compliance, it is believed that Noxturnal Web v2.0 presents no new questions of safety and effectiveness and is substantially equivalent to the features provided by the identified predicate device and the reference device.