



September 24, 2026

CNSAC Medshop GmbH
Arash Kianian
CEO
Biebelrieder St. 42
Theilheim, 97288
Germany

Re: K260949

Trade/Device Name: Disposable Belts for Polysomnography (CNSAC)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: March 21, 2026
Received: March 23, 2026

Dear Arash Kianian:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

**Binoy J.
Mathews -S**

Digitally signed by
Binoy J. Mathews -S
Date: 2026.09.24
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For

James J. Lee, Ph.D.
Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality

Enclosure

Indications for Use

510(k) Number (if known)

K260949

Device Name

Disposable Belts for Polysomnography (CNSAC)

Indications for Use (Describe)

The CNSAC Disposable Belts for Polysomnography is intended to measure thoracic and/or abdominal respiratory effort during polysomnography (PSG) sleep studies in adult and pediatric patients greater than 2 years of age. The device is used with compatible polysomnography recording systems in clinical sleep laboratories or similar diagnostic environments. The belt is intended for single-patient use and is worn externally around the thorax or abdomen over clothing.

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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**510(k) Premarket Notification
CNSAC Disposable PSG Belts**



510(k) SUMMARY

Submitter Information

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Date Prepared: September 24, 2026

Device Name

Trade Name: Disposable Belts for Polysomnography (CNSAC)

Common Name: Ventilatory Effort Recorder Accessory

Classification Name: Breathing frequency monitor

Product Code: MNR

Regulation Number: 21 CFR 868.2375

Device Class: Class II

Predicate Device (K151361)

Primary Predicate: Nox Disposable Inductive Effort Belt

Manufacturer: Nox Medical ehf

Common Name: Ventilatory Effort Recorder Accessory

Classification Name: Breathing frequency monitor

Product Code: MNR

Regulation Number: 21 CFR 868.2375

Device Class: Class II

Device Description

The CNSAC Disposable PSG Belt is a single-patient-use accessory intended for use during polysomnography (PSG) sleep studies to acquire thoracic and abdominal respiratory effort signals when used with compatible respiratory inductance plethysmography (RIP) sensors and PSG recording systems. The device consists of an elastic textile belt incorporating an integrated conductive RIP loop and snap-button connector interface. The belt is designed to be positioned around the patient's thorax and/or abdomen over light clothing during sleep.

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CNSAC Disposable PSG Belts



monitoring procedures. The device is supplied non-sterile and is intended for single-patient use only.

The CNSAC Disposable PSG Belt functions as a passive sensing element within a respiratory effort monitoring system and does not contain active electronics, signal conditioning circuitry, oscillation circuitry, software, firmware, or an internal power source.

During use, the integrated RIP loop is connected to a compatible external RIP sensor through the snap-button connector interface. Changes in thoracic and abdominal circumference during respiration alter the electrical characteristics of the RIP loop. These changes are detected by the external RIP sensor and transmitted to the connected PSG system for signal processing, recording, display, and analysis. The device is available in multiple sizes for adult and pediatric patients (>2 years of age).

The CNSAC Disposable PSG Belt is intended for use by trained healthcare professionals in sleep laboratories, hospitals, and other clinical environments where PSG examinations are performed. The device is used as part of sleep disorder diagnostic procedures, including evaluation of patients with suspected sleep apnea and other sleep-related breathing disorders.

The CNSAC Disposable PSG Belt is intended for use with compatible SOMNOmedics RIP sensors and PSG recording systems, including the SOMNOtouch RESP system. The belt connects to the external RIP sensor through a snap-button interface. Signal acquisition, processing, recording, and display are performed by the connected RIP sensor and PSG system. The belt is a passive accessory and does not contain active electronics, software, firmware, or signal-processing functions.

Indications for Use

The Disposable Belts for Polysomnography (CNSAC) is intended to measure thoracic and/or abdominal respiratory effort during polysomnography (PSG) sleep studies in adult and pediatric patients greater than 2 years of age. The device is used with compatible polysomnography recording systems in clinical sleep laboratories or similar diagnostic environments. The belt is intended for single-patient use and is worn externally around the thorax or abdomen over clothing.

Comparison of Technological Characteristics

The subject device has the same intended use and similar technological characteristics as the predicate device (K151361). Both devices are passive, non-powered accessories used during polysomnography to measure respiratory effort using respiratory inductance plethysmography (RIP) technology.

Both devices consist of an elastic textile belt with an integrated inductive wire and connectors for attachment to PSG monitoring systems. Any minor differences in materials or dimensions do not affect the intended use or fundamental scientific technology and do not raise new questions of safety or effectiveness.

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Feature	New Device	Predicate Device	Substantial Equivalent Comments
	Disposable Belts for Polysomnography (CNSAC)	Nox RIP Belts and Nox RIP Belt Cables	
Manufacturer	CNSAC MedShop GmbH	Nox Medical ehf	
510(k) number	K260949	K151361	
Product code	MNR	MNR	Same as predicate device
Regulation name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Same as predicate device
Regulation number	21 CFR 868.2375	21 CFR 868.2375	Same as predicate device
Device Class	Class II	Class II	Same as predicate device
Indications for use	The Disposable Belts for Polysomnography (CNSAC) is intended to measure thoracic and/or abdominal respiratory effort during polysomnography (PSG) sleep studies in adult and pediatric patients greater than 2 years of age. The device is used with compatible polysomnography recording systems in clinical sleep laboratories or similar diagnostic environments. The belt is intended for single-patient use and is worn externally around the thorax or abdomen over clothing.	The Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems. The Nox RIP Belts are indicated for use on patients greater than 2 years of age. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	Comparable intended use and clinical application. Both devices are intended for measurement of respiratory effort during polysomnography (PSG) in patients greater than 2 years of age. The differences in the described use environments and the additional specification of single-patient use and placement over clothing do not affect safety or effectiveness, as these differences do not alter the device's intended function, operating principle, or method of respiratory effort measurement.
Device Function	Passive accessory used in conjunction with a compatible RIP sensor and PSG system for acquisition of thoracic and abdominal respiratory effort signals	Passive accessory used in conjunction with a compatible RIP sensor and PSG system for acquisition of thoracic and abdominal respiratory effort signals	Same as predicate device
Device Design	Elastic textile RIP belt with integrated conductive wire loop and snap-button connector interface	Elastic textile RIP belt with integrated conductive wire loop and connector interface	Comparable design. Both devices use an elastic textile RIP belt with an integrated conductive wire loop and connector interface for measurement of respiratory effort. Although the connector interfaces are described differently, the difference is related to compatibility with the respective polysomnography (PSG) systems. Both connectors provide the same intended connection function. This difference does not affect the intended function or operating

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			principle and does not raise any new questions of safety or effectiveness.
Technology	RIP belt with integrated conductive/inductive wire loop	RIP belt with integrated conductive/inductive wire loop	Same as predicate device
Functional Components	Textile belt, conductive RIP loop, snap-button connector interface	Textile belt, conductive RIP loop, connector interface	Same technological principle
Power Source / Active Electronics	No power source; contains only passive components	No power source; contains only passive components	Same
Signal Processing	No signal processing done in Belt	No signal processing done in Belt	Same
Sterility	Non-sterile	Non-sterile	Same as predicate device
Environment of Use	Hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	Hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.	Same as predicate device
Intended User	trained healthcare professionals during supervised sleep diagnostic procedures	trained healthcare professionals during supervised sleep diagnostic procedures	Same as predicate device
Target Patient	Adult and pediatric patients (>2 years)	Patients older than 2 years	Same as predicate device
Sizes	Multiple belt sizes available	Multiple belt sizes available	Same as predicate device
Type of connection	Snap connector interface to respiratory effort sensor	Snap connector interface	Same as predicate device
Shelf Life	24 months	Not specified	Comparable. The subject device has a labeled shelf life of 24 months, whereas no shelf life is specified in the cleared labeling of the predicate device. The 24-month shelf life of the subject device is supported by real-time aging evaluation and demonstrates that the device maintains its specified performance and integrity throughout the labeled shelf life. Therefore, the difference in shelf-life labeling does not raise any new questions of safety or effectiveness.
Packaging Configuration	Individual non-sterile packaging	Individual non-sterile packaging	Same as predicate device. Both devices are individually packaged and supplied non-sterile. The packaging configuration is the same and therefore does not affect the safety or effectiveness of the device.

The predicate device K151361 includes both respiratory effort sensing belts (RIP Belts) and associated RIP Belt Cables intended to connect the belts to sleep diagnostic recording systems. In contrast, the subject device consists solely of disposable respiratory effort belts and does not include cables, patient lead wires, recorder interfaces, active electronics, signal conditioning circuitry, software, firmware, or other interconnection accessories.

Accordingly, several technological characteristics evaluated as part of K151361 are not applicable to the subject device, including belt cable performance, recorder interface compatibility, interconnection reliability, and associated accessory requirements. The subject device represents a narrower device configuration consisting solely of the passive respiratory effort belt component of the predicate technology.

The subject device and the predicate RIP Belts share the same intended use, patient population, operating principle, and fundamental technological characteristics. Both devices are passive respiratory effort sensors intended to monitor thoracic and abdominal respiratory effort during sleep studies when used with compatible polysomnography or sleep diagnostic systems. Both devices employ the same fundamental respiratory effort sensing technology, contain no active electronic components, require no power source, and perform no signal processing.

Any differences between the subject device and the predicate device are limited to design, material, dimensional, and manufacturing characteristics that do not alter the intended use, operating principle, or functional performance of the device. Verification testing, performance evaluation, biocompatibility assessment, packaging validation, shelf-life evaluation, and risk management activities demonstrate that these differences do not introduce new hazards, do not adversely affect device performance, and do not raise new questions of safety or effectiveness. Based on the identical intended use, equivalent operating principles, comparable performance characteristics, and reduced technological complexity relative to the complete predicate system, the CNSAC Disposable PSG Belt is substantially equivalent to the legally marketed predicate device cleared under K151361.

Performance Data

Performance Testing

Performance testing was conducted to verify that the CNSAC Disposable PSG Belt performs as intended and to demonstrate substantial equivalence to the predicate device

Mechanical Integrity

Mechanical testing was performed to verify the structural integrity of the elastic belt material and integrated sensing components under conditions representative of intended use. Testing included tensile loading and repeated stretching to evaluate the mechanical integrity of the belt during polysomnography procedures.

Elasticity Testing

The belt was subjected to repeated expansion and contraction cycles to simulate respiratory movements occurring during sleep studies. Testing verified that the device maintained its functional characteristics and mechanical performance following repeated use-related deformation.

Electrical Continuity

The integrated conductive sensing element was evaluated for electrical continuity using resistance measurements. Testing confirmed uninterrupted electrical continuity and functional integrity of the sensing element throughout the intended operating range.

Connector Reliability

The snap-button connector interface was evaluated through repeated connection/disconnection

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cycles and mechanical pull-force testing. Testing verified reliable mechanical retention and electrical connectivity between the disposable belt and compatible respiratory effort sensing components.

Functional Signal Performance Testing

Performance testing was conducted to evaluate the respiratory effort signal performance of the CNSAC Disposable PSG Belt and to compare its performance with the legally marketed predicate device, Nox Respiratory Effort Belt (K151361).

Comparative functional performance testing was performed on five healthy adult volunteers under controlled breathing conditions. Respiratory effort signals were recorded during normal breathing, deep breathing, and rapid breathing using the CNSAC Disposable PSG Belt and the predicate device under equivalent test conditions.

Recorded respiratory effort signals were evaluated with respect to signal acquisition capability, signal continuity, signal stability, waveform morphology, response to changes in respiratory effort and breathing frequency, respiratory pattern recognition, and the presence of signal loss or dropouts.

All predefined acceptance criteria were met. Acceptance criteria included successful acquisition of respiratory effort signals, continuous signal acquisition without clinically significant interruptions or signal loss, stable waveform morphology, and comparable signal response to changes in breathing depth and breathing frequency between the CNSAC Disposable PSG Belt and the predicate device.

Electrical Safety and Electromagnetic Compatibility

The CNSAC Disposable PSG Belt is a passive, non-powered device with no active electronics or wireless functionality. Electrical safety and electromagnetic compatibility were evaluated at the system level with compatible SOMNOmedics PSG equipment. Testing in accordance with IEC 60601-1 and IEC 60601-1-2 included CNSAC Disposable PSG Belt models within the evaluated configurations and demonstrated acceptable electrical safety and EMC performance. The testing supports that use of the belts with the compatible SOMNOmedics system does not adversely affect system electrical safety, electromagnetic compatibility, or respiratory effort signal acquisition.

Shelf-Life Evaluation

Real-time shelf-life evaluation was performed using production belts aged for approximately 36 months to support the labeled 2-year (24-month) shelf life and demonstrate maintenance of device functionality, packaging integrity, and product performance throughout and beyond the claimed storage period.

Biocompatibility

Biocompatibility evaluation was conducted in accordance with ISO 10993 standards, including cytotoxicity, sensitization, and irritation testing, supporting the safety of the materials used.

Clinical Testing

No clinical studies were conducted. Clinical data were not required to demonstrate substantial equivalence, as the device has the same intended use and similar technological characteristics as the predicate device.

Applicable standards/guidance:

- IEC 60601-1 — Medical electrical equipment – Part 1: General requirements for basic

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- safety and essential performance — applicable to the system-level electrical safety evidence.
- IEC 60601-1-2 — Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests — applicable to the system-level EMC evaluation.
 - ISO 10993-1:2018 — Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.
 - ISO 10993-5:2009 — Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
 - ISO 10993-10:2021 — Biological evaluation of medical devices – Part 10: Tests for skin sensitization.
 - ISO 10993-23:2021 — Biological evaluation of medical devices – Part 23: Tests for irritation.
 - FDA Guidance, “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” (September 2023)
 - ISO 14971:2019 — Medical devices — Application of risk management to medical devices

Substantial Equivalence Conclusion

The CNSAC Disposable PSG Belt has the same intended use and similar technological characteristics as the predicate device K151361. Performance testing demonstrates that the device is as safe and effective as the predicate device and does not raise new questions of safety or effectiveness. Therefore, the CNSAC Disposable PSG Belt is substantially equivalent to the predicate device.