August 29, 2025

Neurotronics, LLC
James Smith
Director of Quality and Regulatory
13800 Tech City Circle, Suite 400
Alachua, Florida 32615

Re: K251480
Trade/Device Name: PV01 PVDF Effort Sensor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: SFK
Dated: August 26, 2025
Received: August 26, 2025

Dear James Smith:

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant 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
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)*
K251480

Device Name
PV01 PVDF Effort Sensor

Indications for Use *(Describe)*
The PVDF Effort Sensor is intended to measure and output respiratory effort signals from a patient for archival in a sleep study. The sensor is an accessory to a polysomnography system which records and conditions the physiological signals for analysis and display, such that the data may be analyzed by a qualified sleep clinician to aid in the diagnosis of sleep disorders.

The PVDF Effort Sensor is intended for use on both adults and children by healthcare professionals within a hospital, laboratory, clinic, or nursing home, or outside of a medical facility under the direction of a medical professional.
The PVDF Effort Sensor does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,

- an alarm or alarm system;
- an apnea monitor or apnea monitoring system; or
- life monitor or life monitoring system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter Information

Name:	Neurotronics, LLC
Address:	13800 Tech City Circle, Suite 400 Alachua, FL 32615
Phone:	(352) 372-9955
Primary Contact:	James “Cody” Smith
Title:	Director of Quality and Regulatory
Email:	quality@neurotronics.com

Date Prepared:	August 26, 2025

Regulatory Information

Trade Name:	PV01 PVDF Effort Sensor
Common Name:	PVDF Effort Sensor
Classification Name:	Standard Polysomnograph with Electroencephalograph
FDA Product Code:	SFK
CFR References:	21 CFR 882.1400
Device Classification:	II
Review Panel:	Neurology

Predicate/Reference Devices

	Predicate Device	**Reference Device**
Submission Number:	K173868	K040605
Device Name:	RIP01 RIP Sensor	DYMEDIX Reusable Respiratory Effort Belt Sensor, Model 6015
Manufacturer:	Neurotronics, Inc.	DYMEDIX, Inc.

Subject Device Description

The PV01 PVDF Effort Sensor is a respiratory effort monitoring accessory designed for use during sleep studies to assess breathing patterns by measuring chest and abdominal wall movement. The device functions as an accessory to polysomnography (PSG) systems, enabling qualified sleep clinicians to analyze respiratory data for the diagnosis of sleep disorders.

The sensor consists of two main components: a PVDF (polyvinylidene fluoride) sensor module and an elastic belt. The sensor module contains two plastic enclosures connected by a piezoelectric PVDF sensing element encased in a silicone laminate. The PVDF material generates a tiny voltage that is output through the lead wire to the sleep amplifier. The change in voltage as the tension on the PVDF film fluctuates corresponds to the breathing of the patient. Since the PVDF material generates voltage, the sensor does not require a battery or power from the amplifier. The output signal is processed by the sleep recording system for monitoring and post-study analysis.

The PV01 PVDF Effort Sensor is intended for prescription use only by healthcare professionals in hospitals, sleep laboratories, clinics, nursing homes, or in home environments under medical professional direction. The device is designed for use on both adult and children participating in sleep disorder studies. The sensor is intended to be worn over clothes and not directly on the patient's skin.

Indications for Use

The PVDF Effort Sensor is intended to measure and output respiratory effort signals from a patient for archival in a sleep study. The sensor is an accessory to a polysomnography system which records and conditions the physiological signals for analysis and display, such that the data may be analyzed by a qualified sleep clinician to aid in the diagnosis of sleep disorders.

The PVDF Effort Sensor is intended for use on both adults and children by healthcare professionals within a hospital, laboratory, clinic, or nursing home, or outside of a medical facility under the direction of a medical professional.

The PVDF Effort Sensor does not include or trigger alarms, and is not intended to be used alone as, or a critical component of,

- an alarm or alarm system;
- an apnea monitor or apnea monitoring system; or
- life monitor or life monitoring system.

Substantial Equivalence

Table 1 below compares the Subject Device (PV01 PVDF Effort Sensor), the Predicate Device (RIP01 RIP Sensor, K173868), and the Reference Device (DYMEDIX Respiratory Effort Belt Sensor, K040605). The RIP Sensor was selected as the predicate because it shares the same intended use, and it has similar technological characteristics. Since the Subject and Predicate Devices use different sensing technologies, the DYMEDIX device was included as a reference for performance comparison, as it uses the same PVDF technology as the Subject Device.

Indications for Use

The PV01 PVDF Effort Sensor and the RIP01 RIP Sensor have nearly identical indications for use. Both measure respiratory effort during sleep studies and share the same target population, use environment, and contraindications. Differences do not impact safety or effectiveness. The DYMEDIX sensor also shares the same intended use, though without specific details on population, environment, or contraindications.

Technological Characteristics

All three devices share the same general design, consisting of a sensor module and belt, offering 1.5 mm and keyhole connector options, and providing an identical output signal range. Each relies on the host system for patient isolation and does not require power from the host. The sensing principle differs between the Predicate Device and the Subject/Reference Devices, which lead to some design variations. However, these differences have been evaluated, and none raise new questions of safety or effectiveness.

Table 1: Comparison of Predicate Device

Device Characteristic	**Subject Device PV01 PVDF Effort Sensor**	**Predicate Device RIP01 RIP Sensor (K173868)**	**Reference Device DYMEDIX Respiratory Effort Belt Sensor (K040605)**	**Comparison Analysis:** *Same / Substantially Equivalent / Similar*
510(k) reference	K251480	K173868	K040605	
Device Name	PV01 PVDF Effort Sensor	RIP01 RIP Sensor	DYMEDIX Reusable Respiratory Effort Belt Sensor, Model 6015	
Manufacturer	Neurotronics, LLC	Neurotronics, Inc.	DYMEDIX, Inc.	
FDA Product Code	SFK	OLV	BZQ	The Subject Device uses a new product code under the same CFR Reference as the Predicate Device.
CFR Reference	21 CFR 882.1400 - Electroencephalograph	21 CFR 882.1400 - Electroencephalograph	21 CFR 868.2375 - Breathing frequency monitor	**Same as Predicate**
Device Class	II	II	II	**Same**
Prescription or OTC	Prescription Only	Prescription Only	Prescription Only	**Same**

Indications for Use Statement	The PVDF Effort Sensor is intended to measure and output respiratory effort signals from a patient for archival in a sleep study. The sensor is an accessory to a polysomnography system which records and conditions the physiological signals for analysis and display, such that the data may be analyzed by a qualified sleep clinician to aid in the diagnosis of sleep disorders. The PVDF Effort Sensor is intended for use on both adults and children by healthcare professionals within a hospital, laboratory, clinic, or nursing home; or outside of a medical facility under the direction of a medical professional. The PVDF Effort Sensor does not include or trigger alarms, and is not intended to be used alone as, or a critical component of, • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • life monitor or life monitoring system.	The RIP and Body Position Sensors are intended to measure and output respiratory effort signals and body position, respectively, from a patient for archival in a polysomnography study. The sensors are accessories to a polysomnography system which records and conditions the physiological signals for analysis and display, such that the data may be analyzed by a qualified sleep clinician to aid in the diagnosis of sleep disorders. The RIP and Body Position Sensors are intended for use on both adults and children by healthcare professionals within a hospital, laboratory, clinic, or nursing home; or outside of a medical facility under the direction of a medical professional. The RIP and Body Position Sensors are not intended for the life monitoring of high risk patients, do not include or trigger alarms, and are not intended to be used as a critical component of: • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • life monitor or life monitoring system.	The DYMEDIX, Inc. Reusable Respiratory Effort Belt Sensor and Reusable Limb Movement Sensor are used with existing sleep study recording devices in support of diagnostic recording of respiratory effort and limb movement. The sensors are used with patients who require a sleep study recording.	**Substantially Equivalent** - The Predicate device submission included a Body Position sensor. Besides references to the body position sensor, the indications for use statements are almost identical. The Reference Device has similar indications for use, but does not include any information about patient population, environment of use, or contraindications.

Device Characteristic	**Subject Device PV01 PVDF Effort Sensor**	**Predicate Device RIP01 RIP Sensor (K173868)**	**Reference Device DYMEDIX Respiratory Effort Belt Sensor (K040605)**	**Comparison Analysis:** *Same / Substantially Equivalent / Similar*
Intended Use	Intended to measure and output respiratory effort signals from a patient for archival in a sleep study.	Intended to measure and output respiratory effort signals from a patient for archival in a polysomnography study.	Intended to be used with existing sleep study recording devices in support of diagnostic recording of respiratory effort.	**Same**
Target Population	Adults and Children	Adults and Children	Not specified	**Same as Predicate**
Environment for Use	Used by healthcare professional in a: • Hospital • Laboratory • Clinic • Nursing Home • Outside of a medical facility under the direction of a medical professional	Used by healthcare professional in a: • Hospital • Laboratory • Clinic • Nursing Home • Outside of a medical facility under the direction of a medical professional	Not specified	**Same as Predicate**
Contraindications	Does not include or trigger alarms, and is not intended to be used alone as, or a critical component of, • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • life monitor or life monitoring system.	Is not intended for the life monitoring of high risk patients, does not include or trigger alarms, and is not intended to be used as a critical component of: • an alarm or alarm system; • an apnea monitor or apnea monitoring system; or • life monitor or life monitoring system.	None specified	**Substantially Equivalent** - The Predicate Device states that it is not intended for the "life monitoring of high-risk patients", but this contraindication is covered by the last bullet point for both devices.
Sterility	Non-sterile	Non-sterile	Non-sterile	**Same**
Reusability	The sensor module is reusable. The belt is single use.	Both the sensor module and the belt are reusable.	The sensor module is reusable. The belt is single use.	**Similar -** The Subject and Reference Devices have a single use belt, and all devices have a reusable sensor module
Amplifier Compatibility	Lead wire has options for 1.5mm DIN connectors or keyhole connectors.	Lead wire has options for 1.5mm DIN connectors or keyhole connectors.	Lead wire has options for 1.5mm DIN connectors or keyhole connectors.	**Same**
Sensor Signals	Measures respiratory effort	Measures respiratory effort	Measures respiratory effort	**Same**

Device Characteristic	**Subject Device PV01 PVDF Effort Sensor**	**Predicate Device RIP01 RIP Sensor (K173868)**	**Reference Device DYMEDIX Respiratory Effort Belt Sensor (K040605)**	**Comparison Analysis:** *Same / Substantially Equivalent / Similar*
Typical Signal Range	• 0 - 1000 uV (peak to peak) • 0.1 - 15 Hz	• 0 - 1000 uV (peak to peak) • 0.1 - 15 Hz	• 0 - 1000 uV (peak to peak) • 0.1 - 15 Hz	**Same**
Power Supplied by Host System	No, sensor is passive and requires no internal or external power.	No, sensor is powered through an internal lithium battery.	No, sensor is passive and requires no internal or external power.	**Substantially Equivalent** - None of the devices require power from the host system. The Subject and Reference Devices do not require power at all, and the Predicate Device has an internal battery.
Patient Isolation Provided by Host System	Yes	Yes	Yes	**Same**
Sensing Technology	Uses piezoelectric properties of a polyvinylidene fluoride (PVDF) sensing element and the stretch of a belt to output a waveform which corresponds to the patient's respiratory effort.	Uses respiratory inductance plethysmography (RIP) and the movement of the belt to output a waveform which corresponds to patient's respiratory effort.	Uses piezoelectric properties of a polyvinylidene fluoride (PVDF) sensing element and the stretch of a belt to output a waveform which corresponds to the patient's respiratory effort.	**Similar** - The Subject and Reference Devices use the same technology, and all devices measure the same physiological parameter.
Sensor Application	The belt is connected to one end of the sensor module, then wrapped around the patient's torso, and connected to the other side of the sensor module.	The belt is wrapped around the patient's torso and the ends are buckled together. The sensor module is connected to the belt using a wire set.	The belt is connected to one end of the sensor module, then wrapped around the patient's torso, and connected to the other side of the sensor module.	**Similar -** The difference in sensing technology led to slightly different methods of application. However, all devices have a sensor component and use a belt that wraps around the patient's torso.
Belt Placement	The belt is intended to be placed on the patient's chest or abdomen.	The belt is intended to be placed on the patient's chest or abdomen.	The belt can be placed on the patient's chest or abdomen.	**Same**

Biocompatibility

Biocompatibility testing was not required for the PV01 PVDF Effort Sensor. The sensor is intended to be worn over clothing during overnight sleep studies, resulting in only minimal and incidental skin contact. All external materials, with the exception of the wire set, are identified as very low biocompatibility risk in the FDA Biocompatibility Guidance (Attachment G, Section B). The wire set, however, is identical to that used in the PZ01 Piezo Sensor and TH01 Thermocouple Sensor (K181709), both of which underwent biocompatibility testing. In addition, the wire set, enclosure, and label are composed of the same materials used in the Predicate Device, which has been marketed for more than six years without any reported biocompatibility issues. Based on its limited contact profile and use of established low-risk materials, additional biocompatibility testing for the PV01 PVDF Effort Sensor was not considered necessary.

Performance Testing

The PV01 PVDF Effort Sensor underwent comprehensive verification and validation testing. Functional and performance evaluations, including validation studies, confirmed that the device meets its design specifications and is safe and effective for its intended use. In addition, comparative testing against the Reference Device demonstrated that the PVDF Effort Sensor exhibits equivalent performance under comparable conditions. A summary of testing is provided in Table 2:

Table 2: Summary of Tests Performed

Test	Method	Results
Safety Tests	UL 60601-1:2003 Ed.1 + R:26 Apr 2006 • Dielectric Strength – Section 20.4 • Ingress of Liquids – Section 44.6 • Patient Leads – Section 56.3c)	All tests passed
Usability and Validation Test	Participants performed a sleep study using the Subject Device. The participants filled out a survey about the use and comfort of the device.	All participants rated the sensor high for ease-of-use and comfort. There were no reports of use errors nor adverse events.
Performance Comparison Test	The performance of the Subject Device was compared to the Reference Device. Both devices were placed on a rig that simulated breathing and the cessation of breathing and then their output signals were compared.	The output signals were very similar and clearly showed breathing and the cessation of breathing.
Temperature Range Test	The device was tested at the low and high points of the operating temperature range by observing the output signal.	The output signal met all requirements at both temperatures.

Conclusion

The Subject Device, PV01 PVDF Effort Sensor, is substantially equivalent to the identified predicate device. It shares equivalent indications for use, technological characteristics, and performance attributes. No new questions of safety or effectiveness have been raised based on the differences identified.