November 16, 2018

Neurotronics, Inc.
David Pezet
Quality Manager
4500 NW 27th Ave Ste C2
Gainesville, Florida 32606

Re: K181709
Trade/Device Name: Serenity Piezo Sensor, Serenity Thermocouple Sensor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, GWL, MNR
Dated: October 17, 2018
Received: October 18, 2018

Dear David Pezet:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181709

Device Name
Serenity Piezo Sensor, Serenity Thermocouple Sensor

Indications for Use *(Describe)*
The Serenity Piezo and Serenity Thermocouple Sensors are intended to measure and output snore and limb movement and thermal respiratory flow signals, 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 Serenity Piezo and Serenity Thermocouple 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 Serenity Piezo and Serenity Thermocouple 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K181709 510(k) Summary

November 16, 2018

SUBMITTER

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Contact Person

David Pezet, Quality Manager
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Phone (352)372-9955

SUBJECT DEVICE

Trade Name	Serenity Piezo Sensor Serenity Thermocouple Sensor	
Common Name	Polysomnography (PSG) Accessories:	Piezo Sensor Thermocouple Sensor
Classification	21 CFR 882.1400 Electroencephalograph	
Product Codes	OLV (primary) Standard Polysomnograph with Electroencephalograph GWL Physiological Signal Amplifier MNR Ventilatory Effort Recorder	

Predicate Device K142774

The subject device includes two sensors intended for use with a parent device (Standard Polysomnograph with Electroencephalograph) and is intended to support, supplement, and/ or augment the performance of a parent device. Therefore, the primary predicate is appropriately classified pursuant to the same regulation as its corresponding parent device.

510(k) Number	Submitter/Holder	Device Name	Regulation	Classification Product Codes
K142774	**Neurotronics, Inc.**	Polysmith Sleep System	21 CFR 882.1400 Electroencephalograph Class II	OLV (primary), OLZ, DQA

Reference Devices

These references devices are identified to support the scientific methodology and standard reference values associated with the subject device PSG accessories.

Submitter/Holder	Device Name	Regulation	Classification Product Codes	510(k) Number
Neurotronics, Inc.	Nomad Sleep System Recorder, Model PMU800	882.1835	GWL, DQA, MNR	K092699
S. L. P. Scientific Laboratory Products LTD	Sleepsense Sleep Sensors	868.2375	MNR	K042253
Pro-Tech, Inc.	PLM Sensor	868.2375	BZQ	K940014

DEVICE DESCRIPTION

Serenity sleep sensors are intended to measure and output physiologic signals used for Polysomnography (PSG) or Sleep Studies. These devices are to be used as an accessory to compatible amplifiers.

Typical sleep amplifiers use sensors and electrodes to collect physiological signals to further digitize, and the amplifiers send these signals to a host PC.

Serenity sleep sensors are worn by the patient and connected directly to compatible inputs of an amplifier. The amplifier and related software then processes the signal for review by qualified practitioners to score polysomnograms and diagnose Sleep Disorders.

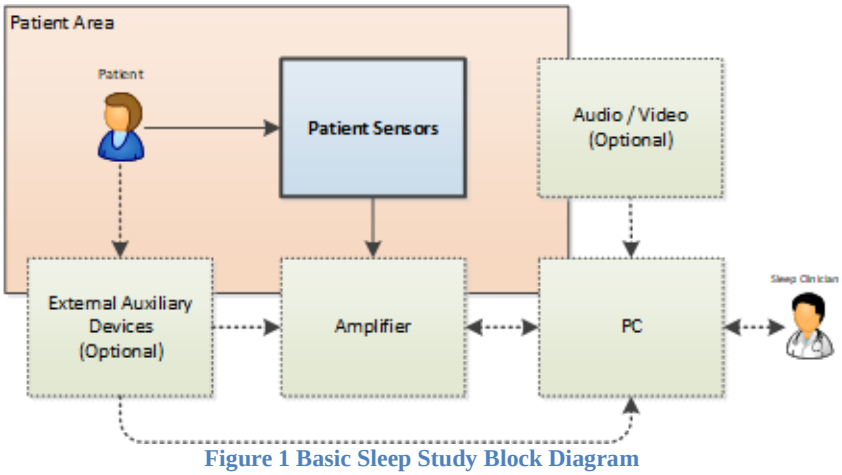
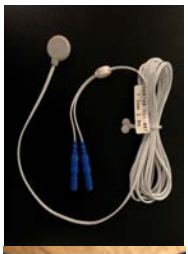


Figure 1 Basic Sleep Study Block Diagram

The **Serenity Piezo Sensor** uses an embedded piezo sensing element to detect the vibrations of snoring or to sense a patient's limb movement. The sensor outputs a signal which corresponds to movements of the limbs or snore vibrations. The Piezo sensor can be placed on the skin or worn in a heel strap.



The **Serenity Thermocouple Sensor** uses thermocouple wire that is joined together to form sensing elements. Thermocouple junctions under each nostril and in front of the mouth output a signal which corresponds to the patient's thermal airflow. The Serenity Thermocouple sensor is available with an optional cannula hanger to aid in patient usability when worn with an airflow pressure cannula.

INTENDED USE

The Serenity Piezo and Serenity Thermocouple Sensors are intended to measure and output snore and limb movement and thermal respiratory flow signals, 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 Serenity Piezo and Serenity Thermocouple Sensors are intended to be used by healthcare professionals for adults and children within a hospital, laboratory, clinic, or nursing home, or outside of a medical facility under the direction of a medical professional.

The Serenity Piezo and Serenity Thermocouple 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.

COMPARISON OF INTENDED USE TO THE PREDICATE DEVICE (PARENT DEVICE TYPE) AND REFERENCE DEVICES (PSG ACCESSORIES AND PHYSIOLOGICAL SIGNAL AMPLIFIER)

Indications for Use

Predicate Device K142774 Neurotronics, Inc. Polysmith Sleep System (includes Sphinx PMU710- Sleep Amplifier)

Rx; The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a sleep study. The physiological signals are recorded and conditioned for analysis and display. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of sleep disorders.

The device is intended for use by healthcare professionals within a hospital, laboratory, clinic, or nursing home; or outside of a medical facility under direct supervision of a medical professional.

The device is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

The device, or any accessory, does not include alarms, and is not intended to be used as a critical component of an alarm system.

The device, or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

The device, or any accessory, is not to be used alone as a life support device or as a critical component of a life support system.

Discussion: Comparison of Intended Use to the Predicate Device K142774

The intended use of the Serenity Piezo and Serenity Thermocouple Sensors is similar to the primary predicate K142774, the parent device type for which they are intended to be an accessory. Both the predicate and subject devices:

- Are intended to be used for archival of a sleep study,
- Are intended for use with adults and children
- Do not include alarms and are not intended to be used as a critical component of an alarm system
- Are not to be used as an apnea monitor or as a component in an apnea monitoring system
- Not to be used as a life support device or a critical component of a life support system

The Sphinx Sleep Amplifier is intended to be used in a medical facility or outside a medical facility under direct supervision of a medical professional, whereas the Serenity sensors are intended to be used in a medical facility or outside at the direction of a medical professional. The limitation of direct supervision by the Polysmith Sleep System is due to the amplifier parent device and not because of the sensors, therefore the Nomad

PMU800 is identified as a reference device since it can be used with the sensors without the limitation of direct supervision.

Reference Device K092699 Neurotronics, Inc. Nomad Sleep System Recorder, Model PMU800

Rx; The Nomad device is a digital amplifier capable of measuring bio-potential signals that may be incorporated into a Polysomnogram.

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study, such as Limb Movement, Respiration Effort, and SpO2.

The data may be analyzed on dedicated Polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders.

This device, or any associated accessories, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

This device, or any associated accessories, is not to be used as a life support device or as a critical component of a life support system.

The device is not sterile.

Discussion: Comparison of Intended Use to Reference Device K092699, also a PSG parent device type cleared under 882.1835 Physiological signal amplifier

The intended use of the Serenity Piezo and Serenity Thermocouple Sensors is similar to the intended use of the reference device Nomad PMU800, also a device type with which the sensors are intended to be as an accessory. Both are intended to be used for archival of a sleep study, not to be used as an apnea monitor or as a component in an apnea monitoring system, not to be used as a life support device or a critical component of a life support system, and are not sterile.

The Nomad PMU800 is also intended to be used in or outside a medical facility at the direction of a medical professional, this is consistent with the intended use of the Serenity Piezo Sensor and Serenity Thermocouple Sensor. The Nomad 510k and Indications for Use statement includes thermal airflow as respiration effort. Use for children or adults, is also described in the 510k summary for K092699.

Reference Device: K042253 S.L.P. LTD. Sleepsense Sleep Sensors

Rx; SleepSense sensors provide a qualitative measure of a patient's physiological parameters for recording onto an FDA-cleared data acquisition system. Their target population: Children and adult patients who are screened during sleep disorder studies. Their environment of use is usually at a sleep laboratory or sometimes at the patient's home.

Discussion: Comparison of Intended Use to Reference Device K042253 Sleep Sense Sensors, cleared under 868.2375 Breathing frequency monitor

The intended use of the Serenity Piezo and Thermocouple Sensor is identical to the S.L.P. LTD. Sleepsense Sleep Sensors. K042253 is also intended to provide a qualitative measure of a patient's physiological parameters for recording onto an FDA-cleared data acquisition system. The target population is also children and adults. The environment of use also includes sleep laboratories and the home.

Reference Device: K940014 Pro-Tech, Inc. PLM Sensor

Rx; The PLM Sensor is intended for use during sleep disorder studies to detect periodic limb movements for recording onto a physiological recorder.

Discussion: Comparison of Intended Use to Reference Device K940014 cleared under 868.2375 Breathing frequency monitor

The Serenity Piezo Sensor can be used as a limb movement sensor, which is the intended use of K940014 Pro-Tech PLM Sensor.

Comparison of Technological Characteristics to Reference Devices (PSG Sensors/ Accessories)

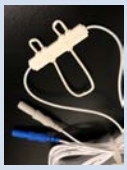
The Neurotronics Serenity Piezo Sensor and Serenity Thermocouple Sensor are similar in design and characteristics. Differences between these devices do not affect the intended use of the subject device for use as PSG accessories.

Piezo Sensor Comparison

Piezo Sensor Comparison		**K042253** **S.L.P. Piezo Sensor (Snore)**	**K940014** **PRO-TECH PLM SENSOR**	**K181709** **Neurotronics Serenity Piezo Sensor**
Image				
Physical Properties	**Size**	~0.80" (21mm) Diameter	~ 0.6" (16mm) Diameter	~ 0.6" (16mm) Diameter
	Sensor Enclosure Material	TPE	TPE	TPE
	Cable Material	PVC	PVC	PVC
Environmental Specifications	**Operating Temperature**	40°F to 104°F (5°C to 40°C)	40°F to 104°F (5°C to 40°C)	50°F to 104°F (10°C to 40°C)
	Operating Relative Humidity	5% to 95% RH non-condensing	15% to 95% RH non-condensing	0 to 93% RH non-condensing

Piezo Sensor Comparison		K042253 S.L.P. Piezo Sensor (Snore)	K940014 PRO-TECH PLM SENSOR	K181709 Neurotronics Serenity Piezo Sensor
	Storage Temperature	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)
	Storage Relative Humidity	5% to 95% RH non-condensing	15% to 95% RH non-condensing	0 to 93% RH non-condensing
Output Specifications	**Comparison Output Signal Testing (Limb)**	Equivalent	Not Applicable	Equivalent
	Comparison Output Signal Testing (Snore)	Not Applicable	Equivalent	Equivalent

Thermocouple Sensor Comparison

Thermocouple Sensor Comparison		K042253 S.L.P. Thermocouple Sensor	K181709 Neurotronics Serenity Thermocouple Sensor
Image			
Physical Properties	**Material**	TPE	TPE
Environmental Specifications	**Operating Temperature**	40°F to 104°F (5°C to 40°C)	50°F to 104°F (10°C to 40°C)
	Operating Relative Humidity	15% to 95% RH non-condensing	0% to 93% RH non-condensing
	Storage Temperature	-4°F to 140°F (-20°C to 60°C)	-4°F to 140°F (-20°C to 60°C)
	Storage Relative Humidity	10% to 95% RH non-condensing	0% to 93% RH non-condensing
Output Specifications	**Comparison Output Signal Testing**	Equivalent	Equivalent

Performance Data

Non-Clinical Testing

Each test identified below includes methodology, criteria, and results for demonstrating performance and safety of the subject device. Neither the S.L.P. Sleepsense Sleep Sensors or Pro-tech sensors are found to publish testing to a standard.

Test Type	Test Method Summary	Results
Electrical Safety	60601-1:2003 Ed.1 + R:26 Apr 2006 • Dielectric Strength • Ingress of Liquids - IPX2 • Patient Leads (21CFR898 Performance Standard for Electrode Lead Wires and Patient Cables)	All samples passed the acceptance criteria. Neither the S.L.P. or Pro-tech sensors were found to publish testing to an electrical safety standard.
Piezo Sensor Verification	Dielectric strength • 1.5 kVAC, 10s ramp, 1 min Signal Level • Movement and vibration clearly visible with recommended configuration. • Output signal within listed specifications. Wire Test • Connector Retention >= 4.5N • Tensile Strength >= 50 N • Leadwire Resistance <= 50 Ohms • Mating Cycles >= 3,650	All samples passed the acceptance criteria. Neither the S.L.P. or Pro-tech sensors were found to publish testing details.
Thermocouple Sensor Verification	Dielectric strength • 1.5 kVAC, 10s ramp, 1 min Signal Level • Oral and Nasal breathing clearly visible at sensitivity of 20. • Output signal within listed specifications. Wire Test • Connector Retention >= 4.5N • Tensile Strength >= 50 N • Leadwire Resistance <= 50 Ohms • Mating Cycles >= 3,650	All samples passed the acceptance criteria. Neither the S.L.P. or Pro-tech sensors were found to publish testing details.
Reference Device Comparison	Piezo Sensor Reference Device Comparison • Sensor snore response to vibration relative to noise floor (SNR) at varied frequencies and complex waveforms using recommended polysomnography montage configuration. • Sensor limb movement response to movement. • Output signal within listed specifications. Thermocouple Sensor Reference Device Comparison • Sensor response as warm air passes over for controlled periods of time using	Comparison testing shows equivalent performance of the Serenity sensors and the reference devices using the same host system configurations. Neither the S.L.P. or Pro-tech sensors were found to publish comparison information.

Test Type	Test Method Summary	Results
	recommended polysomnography montage configuration. • Signal cessation attenuated by >=90% of pre-event baseline. • Output signal within listed specifications.	
Biocompatibility	• ISO 10993-1 Fourth edition 2009-10-15 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 10993-10:2010 Biological Evaluation of Medical Devices - Part 10, Tests for Irritation and Skin Sensitization	All samples passed the acceptance criteria for the performed biocompatibility testing. Neither the S.L.P. or Pro-tech sensors were found to publish biocompatibility.
Sterility	Not applicable	Neither the S.L.P. or Pro-tech sensors were found to publish sterility information.

CONCLUSION

Based on the comparisons of the intended use and technological characteristics, as well as the results of the comparative testing, the Serenity Piezo Sensor and Serenity Thermocouple Sensors are substantially equivalent to the predicate.