



July 2, 2018

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

Re: K173868

Trade/Device Name: Serenity Body Position Sensor and Serenity RIP Sensors
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV
Dated: June 5, 2018
Received: June 8, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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

Indications for Use

510(k) Number (if known)

K173868

Device Name

Serenity Body Position Sensor and Serenity RIP Sensors

Indications for Use (Describe)

The Serenity RIP and Serenity 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 Serenity RIP and Serenity 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 Serenity RIP and Serenity 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.

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."

5 510(k) Summary

5.1 SUMMARY DATE:

June 5, 2018

5.2 510K SUBMITTER:

Neurotronics, Inc.
4500 NW 27TH AVE STE C2
Gainesville, FL 32606

Phone: 352.372.9955
Fax: 815.550.2871

5.2.1 Primary Contact:

Name: David Pezet
Email: quality@neurotronics.com

Title: Quality Manager
Phone: 352.372.9955

5.2.2 Establishment Registration Number: 1063925

5.3 DEVICE TYPE (COMMON NAME):

Body Position Sensor
Respiratory Inductance Plethysmography (RIP) Sensor

5.4 PROPRIETARY NAME OF THE DEVICE:

Serenity Body Position Sensor and Serenity RIP Sensors

5.5 CLASSIFICATION:

5.5.1 Product Code

It is recommended the Serenity Body Position Sensor and Serenity RIP Sensor be classified as a Class II device by the Neurology Panel under 21 CFR Part 882.1400 “Neurological Diagnostic Devices”, product code OLV “Standard Polysomnograph With Electroencephalograph”.

Serenity Body Position Sensor

Product Code	Device	Regulation Description	Regulation Number
OLV	Standard Polysomnograph With Electroencephalograph	Electroencephalograph	882.1400

Serenity RIP Sensor

Product Code	Device	Regulation Description	Regulation Number
OLV	Standard Polysomnograph With Electroencephalograph	Electroencephalograph	882.1400

5.5.2 Predicate Device

Submitter/Holder	Device Name	Regulation	Classification(s)	510(K)
Neurotronics, Inc.	Polysmith Sleep System	882.1400	OLV, OLZ, DQA	K142774

Reference Devices

Submitter/Holder	Device Name	Regulation	Product Codes	510(K)
Neurotronics, Inc.	Nomad Sleep System Recorder, Model PMU800	882.1835	GWL, DQA, MNR	K092699
Braebon Medical Corp.	Ultima Body Position Sensor	882.5050	LEL	K981969
Ambu A/S	RIPmate; Sleepmate Respiratory Effort Sensor	868.2375	BZQ	K903300

5.6 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 studies use sensors and electrodes to collect, digitize, and send physiological 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

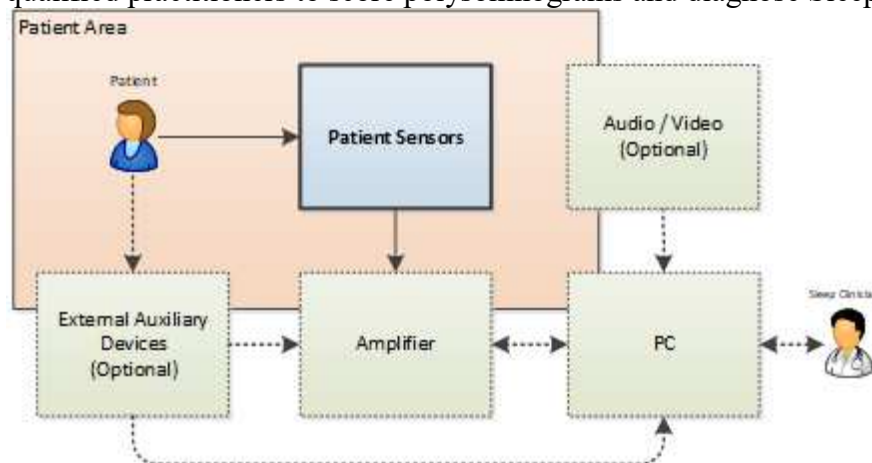


Figure 1 Basic Sleep Study Block Diagram

The Serenity Body Position uses a 3-axis accelerometer to track the patient's body orientation; outputting a voltage which corresponds to one of 5 positions (sitting/upright, supine, prone, left-side, and right-side).



The Serenity RIP Sensor uses respiratory inductance plethysmography to output a waveform which corresponds to patient's respiratory effort. The patient wears an adjustable elastic belt which connects to the RIP driver, the RIP driver then connects to the host device. The Serenity RIP sensor is available for both thorax and abdomen. Thorax and abdomen versions are identical, except that they operate at different frequencies to avoid interference.



5.7 INTENDED USE

The Serenity 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 Serenity 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 Serenity 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.

5.8 PREDICATE COMPARISON

5.8.1 Intended Use Comparison

K142774 Neurotronics, Inc. Polysmith Sleep System Intended Use (includes Sphinx PMU710)

“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.”

Neurotronics Serenity Body Position and RIP Sensor Intended Use Comparison Discussion

The intended use of the Serenity Body Position and Serenity RIP Sensors does not conflict with the intended use of the primary predicate, the device type which it is intended to be an accessory to. Both are intended to be used for archival of a sleep study, for use with adults and children, do not include alarms or are intended to be used as a critical component of an alarm system, not to be used as an apnea monitor or as a component in an apnea monitoring system, and not to be used as a life support device or a critical component of a life support system.

Although the Sphinx is intended to be used within a medical facility, or outside a medical facility under direct supervision of a medical professional, the Serenity sensors are intended to be used within or outside a medical facility at the direction of a medical professional. The limitation of direct supervision by the Polysmith Sleep System is due to the amplifier and not because of the sensors; therefore, the Nomad PMU800 is also included as a reference device.

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

Intended Use Comparison

“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.”

Neurotronics Serenity Body Position and RIP Sensor Intended Use Comparison Discussion

The intended use of the Serenity Body Position and Serenity RIP Sensors does not conflict with the intended use of the reference device Nomad PMU800, also a device type which it is intended to be an accessory to. 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 is 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 Body Position Sensor and Serenity RIP Sensor. Although the Nomad Indications for Use statement does not include body position, or use for children or adults, these are described in the 510k summary for K092699.

K981969 Braebon Medical Corporation Ultima Body Position Sensor Intended Use

“The Braebon Medical Corporation Ultima Body Position Sensor is intended for use during sleep disorder studies as an indicator of body position. The sensor uses a three-volt lithium battery and plugs directly into either a DC amplifier or multiplexer.

The target population of the Ultima Body Position Sensor is all children and adult patients who are screened during sleep disorder studies. The majority of the screening occur at a sleep laboratory although the sensor can also be used in home studies.

The Ultima Body Position Sensor is intended for use only by or on the order of a physician. “

Neurotronics Serenity Body Position Sensor Intended Use Comparison Discussion

The Serenity Body Position Sensor intended use is identical to the Ultima Body Position Sensor. It is also intended to be used to indicate body position during sleep disorder studies. The target population is also both children and adults. The study environment also includes both sleep laboratories and the home. Both the Ultima Body Position Sensor and the Serenity Body Position Sensor are intended for use only by or under the order of a physician.

K903300 Ambu RIPmate; Sleepmate Respiratory Effort Sensor Intended Use

“The Ambu Sleepmate respiratory effort sensor is intended to detect respiratory effort from chest or abdomen movement during sleep research and clinical studies of sleep. This Belt is intended for use in supervised medical settings.”

Neurotronics Serenity RIP Sensor Intended Use Comparison Discussion

The Serenity RIP Sensor share the same intended use as the Ambu RIPmate. Both are intended to detect respiratory effort of the chest or abdomen during sleep in a supervised medical setting. The Serenity RIP Sensor additionally, is intended for use outside of a medical setting under the direction of a medical professional.

5.8.2 Technical Comparison

The Neurotronics Serenity Body Position Sensor and Serenity RIP Sensor share similar design form and characteristics. Of the differences, none are considered to effect intended use or safety and effectiveness.

Body Position Sensor Comparison

Body Position Sensor Comparison		Braebon Ultima Body Position Sensor	Neurotronics Serenity Body Position Sensor
Image			
Physical Properties	Battery	3V Lithium	3V Lithium
	Battery Life	~2 years	> 2 years
Environmental Specifications	Operating Temperature	41°F – 90°F (5°C-32°C)	50°F - 104°F (10°C - 40°C)
	Operating Relative Humidity	10% to 95% RH non-condensing	0 to 93% RH non-condensing
	Storage Temperature	32°F to 140°F (0°C to 60°C)	-4°F to 140°F (-20°C to 60°C)
	Storage Relative Humidity	10%-95% RH non-condensing	0 - 93% RH non-condensing
	Pressure	Not Specified	70.0 kPa to 106 kPa
Output Specifications	Output Signal	0 V to 1 V (± 0.1 V)	0 V to 0.78 V ($\pm 10\%$)
	Positions Detected	Right Side Left Side Supine Prone Upright (Sitting)	Right Side Left Side Supine Prone Sitting (Upright)

RIP Sensor Comparison

RIP Sensor Comparison		Ambu RIPmate	Neurotronics Serenity RIP Sensor
Image			
Physical Properties	Belt Length	Adjustable 24" to 79" (60 cm to 200 cm)	Adjustable Small 15" to 27" (38.1 cm to 68.58 cm) Medium 21" to 45" (53.34 cm to 114.3 cm) Large 32" to 78" (81.28 cm to 198.12 cm)
	Belt Material	Elastic Band with Insulated wire	Elastic Band with Insulated wire
	Cable Length	2.05 m	0.6m ± 2 cm or 2.0m ± 5 cm
	Cable Material	PVC jacketed; ZIP-style cord	PVC jacketed; ZIP-style cord
	Module	Box: ABS Cable: PVC jacketed; ZIP-style cord	Box: ABS Cable: PVC jacketed; ZIP-style cord
	Battery	3V Lithium	3V Lithium
	Battery Life	Estimated 3000 hours	> 3000 hours
Environmental Specifications	Operating Temperature	40°F – 120°F (5°C-50°C)	50°F - 104°F (10°C - 40°C)
	Operating Relative Humidity	15%-95% RH non-condensing	0 - 93% RH non-condensing
	Storage Temperature	0°F-120°F (-20°C-50°C)	-4°F - 140°F (-20°C - 60°C)
	Storage Relative Humidity	10%-95% RH non-condensing	0 - 93% RH non-condensing
	Pressure	50.33 kPa – 199.48 kPa	70.0 kPa - 106 kPa
Output Specifications	Output Signal	Maximum: ±5mV	Maximum: Not Specified. Nominal: ~ ±1mv

5.8.3 Performance Data

5.8.4 Testing Data

Each referenced document identifies the methodology, criteria, and results for assessing performance and safety characteristics of the applicable device in compliance with Neurotronics design control processes. See section 11.6 Verification for testing related information. Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate are found to publish testing to a standard. The design for both the Neurotronics Serenity Body Position Sensor and the Neurotronics Serenity RIP Sensor are tested to 60601-1 C1:2009/(R)2012 And A2:2010/(R)2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

Test	Test Method Summary	Results
60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Humidity Preconditioning Determination of Applied Part and Accessible Parts Legibility of Marking Durability of Marking Patient Leakage Current Dielectric Voltage Withstand Resistance to Heat Excessive Temperature Ingress of Liquids – IEC 60529 Cleaning, Disinfection and Sterilization of ME Equipment and ME Systems Enclosure Mechanical Strength Push Impact Drop Test Hand-Held ME Equipment Mold Stress Relief	All samples passed the acceptance criteria. Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish testing to a basic safety standard.
IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility	Radiated Emissions CISPR11 ed5.0 (with A1:2010) Electro-Static Discharge Immunity Test IEC 61000-4-2 ed2.0 (2008-12) Conducted, Radio-Frequency, Electromagnetic Immunity Test IEC 61000-4-6 ed2.0 (with A1:2004+A2:2006) Power Frequency Magnetic Field Immunity Test IEC 61000-4-8 ed2.0 (2009-09)	All samples passed the acceptance criteria. Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish testing electromagnetic compatibility.

Body Position Sensor Verification	Position test Dielectric strength Transition and Hysteresis Output Impedance Operational Battery Life Calculation Dimensional Analysis Output Noise Connector Tests Strap Fasten/Unfasten Cycle Wire Construction Test Operational Battery Voltage Range Test	All samples passed the acceptance criteria. Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish testing details.
Reference Device Comparison	Body Position Sensor Reference Comparison Test RIP Sensor Reference Device Comparison	Comparison testing shows equivalent performance of the Serenity sensors and the reference devices, using the same host system configurations. Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish comparison information.
Biocompatibility	Not Applicable	Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish biocompatibility.
Sterility	Not applicable	Neither the Braebon Ultima Body Position Sensor or the Ambu RIPmate were found to publish sterility information.

5.9 CONCLUSION

Based on the results of the Intended Use Comparison, the Technical Comparison, and Testing Data, it is believed that the Serenity Body Position Sensor and Serenity RIP Sensors present no new questions of safety and effectiveness and, are substantially equivalent to the identified predicate. Both sensors have similar physical, electrical, and environmental designs. Both share the same intended use.