June 24, 2019

Neurovirtual USA, INC.
Eduardo Faria
CEO
2315 NW 107th Ave Suite# 1M27
Doral, Florida 33172

Re: K171304
Trade/Device Name: Maxxi Rip Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: May 17, 2019
Received: May 22, 2019

Dear Eduardo Faria:

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/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 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 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,

for James J. Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171304

Device Name
Maxxi Rip Sensor

Indications for Use *(Describe)*
Maxxi RIP Sensor is intended for measuring of respiratory effort signals. They function as accessories for sleep/ polysomnography (PSG) systems.
The device is offered in different sizes to be used on adult patients.
The intended environments are hospitals, institutions, sleep centers or sleep clinics.

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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Neurovirtual USA Inc.
3303 W Commercial Blvd Suite #100
Fort Lauderdale, FL 33309 - USA
Phone: (786) 693-8200 – Fax (305) 393-8429

Section 5
510(k) SUMMARY

A) Submitter's Name: Neurovirtual USA, Inc.

Owner / Operator Registration Number: 9091724
Manufacture Registration Number: 3006136239

B) Address: 3303 W Commercial Blvd #100
Fort Lauderdale, FL 33309 USA

C) Phone and Fax Numbers
Phone: (786) 693-8200
Fax: (305) 393-8429

D) Contact Person: Eduardo J. Faria

E) Preparation Date: June 21, 2019

F) Classification Name:
Common / Usual Name: Ventilatory effort recorder
Proprietary Name: Maxxi Rip Sensor
Product Code: MNR
Class: Class II
Regulation: 21 CFR 868.2375

G) Device Description

Maxxi Rip Sensor is a device intended to capture respiratory effort from a patient and output the signal to a PSG device for sleep studies. This signal is captured using an elastic belt fastened around the thorax or abdomen that will exhibit a change in tension as the thorax or abdomen expands or contracts. This change in tension is measured and converted to a signal output by the interface and processed by a PSG device.
The product is composed of 3 major parts, the interface box, the cable and the belt.
Cables are used to connect between the respiratory effort sensor (RIP belts) and the applicable sleep recorder/polysomnography (PSG) system.
The device is offered in different sizes to be used on adult patients.
The Maxxi Rip was validated with Neurovirtual BWMini PSG device recorder only, therefore we don't guarantee compatibility with other devices.

H) Substantial Equivalence:

The Maxxi Rip Sensor is equivalent with the following products:

510(k) Number	Model	Company
K151361	Nox RIP Belts	Nox Medical ehf

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1. Indications for Use:

Indications for Use Comparison	
Neurovirtual Maxxi Rip Sensor	**Nox Medical ehf** Nox RIP Belts
Maxxi RIP Sensor is intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems. The device is offered in different sizes to be used on adult patients. The intended environments are hospitals, institutions, sleep centers or sleep clinics.	Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems. The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home.

2. Technological Characteristics Comparison:

The predicate devices used to establish substantial equivalence for the Maxxi Rip Sensor is outlined below. This section of this submission will provide a comparison of design, materials, and technical specifications of the Maxxi Rip Sensor to each of the predicate devices stratified by functional modality.

Specifications Comparison			
Device Brand and Common Name	**Neurovirtual** Maxxi Rip Sensor	**Nox Medical ehf** Nox RIP Belts	**Comments**
510(k) Number	K171304	K151361	NA
Classification	MNR	MNR	Identical
Regulation #	21 CFR 868.2375	21 CFR 868.2375	Identical
Classification Name	Ventilatory effort recorder	Ventilatory effort recorder	Identical
Patient Population	Indicated for use on patients greater than 2 years of age	Indicated for use on patients greater than 2 years of age	Identical
Prescription Use	YES	YES	Identical
Mechanism of action/Principle of operation	respiratory inductance plethysmograph	respiratory inductance plethysmograph	Identical
Intended Environment Use	hospitals, institutions, sleep centers or sleep clinics	hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient´s home	Equivalent
Type of modules	RIP Belt and Interface	Rip Belt and Interface	Identical
Frequency Response	0-1Hz	Not declared	Equivalent
Disposable	RIP Belts: Disposable Interface and Cable: Reusable Adjustable Belt: Reusable	RIP Belts: Disposable Interface and Cable: Reusable	Equivalent
Shelf life	10 years	Not declared	Equivalent
Dimensions	50.80 x 36.50 x 18.90 mm	Not declared	Equivalent
Different belt sizes	YES from X-Small to X-Large	YES from X-Small to X-Large	Identical
RIP Belt Material	Polyester/Dorlastan ABS Buckles Nylon – Velcro	Polyester/Dorlastan	Equivalent
Cables Material	PVC – plastic injection	- PVC – wire jacket	Equivalent

	TPE – device end strain relief TPU - wire jacket Ni plated stainless steel – snaps	- ABS/PC – belts end - TPE – device end strain relief - Gold plated stainless steel – snaps	
Interface Enclosure Material	Plastic ABS enclosure Electronic components Printed Circuit board	ABS plastic	Equivalent
Connection to Patient	Around the abdomen or thorax	Around the abdomen or thorax	Identical
Type of Equipment to Be Connected to	Sleep recorder	Sleep recorder	Identical
Connector Type	Monopolar DIN 42-802 touch proof	Nox proprietary RIP snaps	Equivalent
Signals Measured	Respiratory Effort (Abdomen and Thorax)	Respiratory Effort (Abdomen and Thorax)	Identical
Respiratory Effort Technology	RIP (Respiratory Inductive Plethysmography) technology	RIP (Respiratory Inductive Plethysmography) technology	Identical
Power Source	Not intended to be connected to the power grid	Not intended to be connected to the power grid	Identical
Isolation	No component included in the RIP Belts that are relied on as means of protection	No component included in the RIP Belts that are relied on as means of protection	Identical
Applicable Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Identical
Packing	Plastic bag	Plastic bag	Identical

Discussion: As showed above the comparison shows that Maxxi Rip Sensor was developed to be substantial equivalent to the predicate, despite the small differences in the intended environment use and material the subject device does meet the performance criteria when compared with the predicate demonstrating substantially equivalence.

I) Performance Testing Summary:

1. Safety and Effectiveness Testing

The Maxxi Rip was submitted to standard IEC 60601-1 test which resulted in full compliance as reported in the test reports.

2. EMC Testing

The Maxxi Rip was submitted to electromagnetic compatibility test, standard IEC 60601-1-2 which resulted in full compliance as reported in the test reports.

3. Risk Analysis

The Maxxi Rip was developed according to the ISO14971 for appropriate actions related to risks found during the development to reach appropriate performance, safety and substantially equivalence with the predicate.

4. Signal Quality and Comparison Testing:

Signal integrity tests were conducted for the Maxxi Rip Sensor with focus on signal to noise ratio, signal range, bandwidth and linearity and the test results compared to the signal integrity test conducted for the predicate NOX-RIP.

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5. Performance Testing:

The performance test is executed for certain % amount of the products manufactured. This phase is necessary to identify possible flaws with the product and manufacturing process mistakes.

Performance Test protocol	Description	Acceptance Criteria
Belt Signal Verification	Verify the signal output stretching and releasing the inductive belt in order to get a sine wave form in the output.	The signal must have a clean sine wave form following the belts stimulation. Devices with showing the signal output with interreferences will be rejected.
Belt Dimensions	Verify if the dimensions of the belts in rest are within the acceptable range in accordance with the product specifications.	Smaller adjustment: 900mm Lager adjustment: 1200mm Allowance: +-10%
Belt Connectivity	Using a multimeter in continuity scale, check if the internal belt wiring has connectivity.	Not allowed false contact, or no connectivity.
Belt Visual Conditions	Verify the visual aspects of the product. Any scratches, ruptures, wrong labels, oxidation, packing flaws, and connector conditions will be rejected.	All damage types are not allowed, products with scratches, wire ruptures, wrong labeling, oxidation, packing flaws or connector issues will be rejected and not put to sales.
Cable Dimensions	Verify if the cable length is within the acceptable range.	Cable A: 250mm Cable B: 2000mm Allowance: +-5%
Cable Connectivity	Using a multimeter in continuity scale, check if the cable has connectivity.	Not allowed false contact, or no connectivity.
Cable Visual Conditions	Verify the visual aspects of the product. Any scratches, ruptures, wrong labels, oxidation, packing flaws, and connector conditions will be rejected.	All damage types are not allowed, products with scratches, wire ruptures, wrong labeling, oxidation, packing flaws or connector issues will be rejected and not put to sales.
Interface functional test	Verify if the signal output from the pre-approved belt is working properly.	The signal must have a clean sine wave form following the belts stimulation. Devices with showing the signal output with interreferences will be rejected.
Interface Visual Conditions	Verify the visual aspects of the product. Any scratches, ruptures, wrong labels, oxidation, packing flaws, and connector conditions will be rejected.	All damage types are not allowed, products with scratches, wire ruptures, wrong labeling, oxidation, packing flaws or connector issues will be rejected and not put to sales.

Conclusion: Based on the performance test applied to this Maxxi Rip Sensor and the predicate comparison, we conclude that the quality and performance for the specified Indications for use for this product was reached as well the substantially equivalency to the predicate.