January 16, 2020

Neurovirtual USA, INC.
Eduardo Faria
CEO
3303 W Commercial Blvd #100
Fort Lauderdale, Florida 33309

Re: K191095
Trade/Device Name: Maxxi Snore Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: December 27, 2019
Received: December 31, 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 Michael Ryan
Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191095

Device Name
Maxxi Snore Sensor

Indications for Use *(Describe)*
The Maxxi Snore Sensor is a device intended to acquire snore bursts. It responds to snoring and other sounds in the audio range picked up through the skin and convert them to a small analog voltage that provides an indication of the presence of these sound/vibration bursts. This sensor is intended to be used with polysomnography devices and adult patients. Intended to be use in a sleep laboratory, clinics or hospitals.

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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Neurovirtual USA Inc.
3303 W Commercial Blvd #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: 3006125362

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: December 27, 2019

F) Classification Name:
Common / Usual Name: Breathing frequency monitor
Proprietary Name: Maxxi Snore Sensor
Product Code: MNR
Class: Class II
Regulation: 21 CFR 868.2375

G) Device Description:

MAXXI SNORE SENSOR piezo electric based sensors detect sound and vibration of the snore through skin contact. The sensor is placed on the patient neck surface where it can easily detect the snoring bursts during the sleep study.

The product is offered in 2 different length sizes, 3ft and 7ft.

The sensor is compatible with any recording device with the DIN 42-802 receptacle which is the gold standard for PSG recording machines.

H) Substantial Equivalence:

The Maxxi Snore Sensor is equivalent with the following products:

510(k) Number	Model	Company
K941759	SNORING SENSOR	S.L.P. Ltd. *Former EPM INFORMATION SYSTEMS, INC.*

Neurovirtual USA Inc.
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1. Indications for Use/Intentions for Use:

Intention for Use Comparison	
Neurovirtual Maxxi Snore Sensor	**S.L.P. Ltd.** Snoring Sensor
The Maxxi Snore Sensor is a device intended to acquire snore bursts. It responds to snoring and other sounds in the audio range picked up through the skin and convert them to a small analog voltage that provides an indication of the presence of these sound/vibration bursts. This sensor is intended to be used with polysomnography devices and adult patients. Intended to be use in a sleep laboratory, clinics or hospitals.	The Snoring Sensor is a device intended to acquire snore bursts. It responds to snoring and other sounds in the audio range picked up through the skin and convert them to a small analog voltage that provides an indication of the presence of these sound/vibration bursts. This sensor is intended to be used with polysomnography devices and adult patients. Intended to be use in a sleep laboratory, clinics or hospitals.

2. Technological Characteristics Comparison:

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

Technological Characteristics Comparison		
Device	**Neurovirtual** Maxxi Snore Sensor	**S.L.P. Ltd.** Snoring Sensor
510(k) Number	K191095	K941759
Classification	BZQ	BZQ
Target population	Adults	Adults
Environment	sleep laboratory, clinics or hospitals	sleep laboratory, clinics or hospitals
Principle of operation	The mechanism of snoring is vibration of anatomical structures in the pharyngeal airway. The sensor is placed on the side of the patient neck in order to capture the movement or vibration during the snore's events. Crystalline materials produce small amounts of electricity when a force is applied that changes their shape in some way. These are called piezoelectric materials. When the small amounts of vibration applied to the Maxxi Snore crystal, a small voltage is produced for a PSG device amplify and display the signal in the sleep study. The signal output for snoring is called snore bursts. Based on the snore signals during the	The mechanism of snoring is vibration of anatomical structures in the pharyngeal airway. The sensor is placed on the side of the patient neck in order to capture the movement or vibration during the snore's events. Crystalline materials produce small amounts of electricity when a force is applied that changes their shape in some way. These are called piezoelectric materials. When the small amounts of vibration applied to the Maxxi Snore crystal, a small voltage is produced for a PSG device amplify and display the signal in the sleep study. The signal output for snoring is called snore bursts. Based on the snore signals during the

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	sleep study the physician will qualify, quantify and along with the other sleep parameters determine the diagnose of the sleep disorder.	sleep study the physician will qualify, quantify and along with the other sleep parameters determine the diagnose of the sleep disorder.
Parent device	To work in conjunction with a polysomnography device.	To work in conjunction with a polysomnography device.
Mechanical application	Sensor is placed on patient's neck	Sensor is placed on patient's neck
Structure	Piezo-electric element covered by TPC plastic injection with a wire to connect to the PSG amplifier.	Piezo-electric element covered by TPC plastic injection with a wire to connect to the PSG amplifier.
Contact Material	Thermoplastic elastomers (TPC-ETs)	Thermoplastic elastomers (TPC-ETs)
Wire Material	Insulated Teflon wire	Insulated Teflon wire
Wire Colors	White	White
Connector	DIN 42-802 touch proof	DIN 42-802 touch proof
Signal output	AC signal	AC signal
Signal Frequency range	0-500 HZ	0-500 HZ
Amplitude sensitivity range	0-500uV	0-500uV
Sensor diameter	18mm	18mm
Cable length	3ft and 7ft	3ft and 7ft
Package	Plastic bag	Plastic bag
Image		

Discussion: The Maxxi Snore and the predicate device Snoring Sensor manufactured by S.L.P Ltd., are substantially equivalent in technology, function, and intended use: both sensors are indicated to provide snoring signal for sleep disordered breathing; both devices use the same method of action; both devices use equivalent material and both devices provide equivalent output signals.

I) Applied Standards:

In order to reach high quality and effectiveness the Maxxi Snore Sensor is produced in compliance with the quality management standard ISO 13485:2003, "Medical Devices, Quality Management Systems: Requirements for Regulatory Purposes" and FDA GMP "Good Manufacturing Practices".

ISO 10993 for Cytotoxicity, Skin Sensitization and Irritation Studies

IEC 60601-1, IEC 60601-1-1

J) Performance Testing:

The test performance comparing the Maxxi Snore and the predicate device Snoring Sensor manufactured by S.L.P Ltd was performed and the summary results are show below.

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Test	Description	Criteria	Results
Parts Dimensions	Verify if the dimensions of the Piezo electric unit are within the acceptable range and equivalent to the predicate	Allowance: +-10%	The dimensions of the piezo electric unit are within the acceptable criteria as when compared to the predicate device.
Cable Length	Verify if the cable length is within the acceptable range and equivalent to the predicate	Expected: 3 ft and 7 ft Allowance: +-5%	The cable length of the sensor is within the acceptable criteria as when compared to the predicate device.
Visual Conditions	Verify the visual aspects of the product and equivalency with the predicate. Cable aspects, labeling, flexibility, plastic finishing, and connector conditions.	All aspects must be substantially equivalent to the predicate device.	Maxxi Snore sensor was inspected, and the result is equivalent to the predicate device.
Output signals Frequency and Amplitude Tests	The sensor Maxxi Snore and the predicate Snoring Sensor were connected to the same PSG recorder and the acquired data was compared in frequency and amplitude.	Allowance: +-15%	Both sensors acquired equivalent signals within the acceptable range.

Discussion: The Maxxi Snore and the predicate device Snoring Sensor manufactured by S.L.P Ltd., are substantially equivalent in technology, function, and intended use: both sensors are indicated to provide respiratory signal for sleep disordered breathing; both devices use the same method of action; both devices use equivalent material and both devices provide equivalent output signals.