December 14, 2020

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

Re: K201495
Trade/Device Name: Maxxi Flow Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: November 10, 2020
Received: November 12, 2020

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 Malvina B. Eydelman, M.D.
Director
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)*
K201495

Device Name
Maxxi Flow Sensor

Indications for Use *(Describe)*
The Maxxi Flow sensor is a respiratory sensor. It is placed under the patient's nostrils and produce a signal that is directly proportional to the temperature changes of air inhaled and exhaled during respiration. Maxxi Flow sensors generate a small analog electrical signal that provides a clear, reliable indication of respiration airflow. 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

510(k) SUMMARY

Submitter's Name: Neurovirtual USA, Inc.

Owner / Operator Registration Number: 3006125362
FEI Number: 3006125362
Manufacture Registration Number: 3006125362

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

Phone and Fax Numbers

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

Contact Person: Eduardo J. Faria

Preparation Date: December 11, 2020

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

Device Description:

MAXXI FLOW SENSOR Thermocouple based sensors detect change of breath temperature between ambient temperature (inhalation) and lung temperature (exhalation). A thermocouple placed in front of a nostril detects breathing as a temperature change.

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

Maxxi Flow sensor is compatible with Neurovirtual PSG devices.

Substantial Equivalence:

The Maxxi Flow Sensor is substantial equivalent with the following products:
Primary Predicate

510(k) Number	Model	Company
K922112	Thermocouple Flow Sensor (Easy Flow)	S.L.P. Ltd. *Former EPM INFORMATION SYSTEMS, INC.*

Reference device**:**

510(k) Number	Model	Company
K981445	ULTIMA AIRFLOW SENSOR	BRAEBON MEDICAL CORP.

The reference predicate was added in order to support to demonstrate the substantial equivalence with the subject device because it has similar anatomical, mechanical and technological characteristics, as well it is not powered with battery which is the same as the subject device.

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1. Indications for Use:

Indications for Use Comparison		
Neurovirtual Maxxi Flow Sensor	**S.L.P. Ltd.** Thermocouple Flow Sensor (Easy flow)	**Braebon** **ULTIMA AIRFLOW SENSOR**
The Maxxi Flow sensor is a respiratory sensor. It is placed under the patient's nostrils and produce a signal that is directly proportional to the temperature changes of air inhaled and exhaled during respiration. Maxxi Flow sensors generate a small analog electrical signal that provides a clear, reliable indication of respiration airflow. 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 Easy flow sensor is a respiratory sensor. It is placed under the patient's nostrils and produce a signal that is directly proportional to the temperature changes of air inhaled and exhaled during respiration. Easy flow sensors generate a small analog electrical signal that provides a clear, reliable indication of respiration airflow. This sensor is intended to be used in polysomnography devices Intended to be use in a sleep laboratory, clinics or hospitals	A Qualitative measure of respiratory airflow for recording onto a data acquisition system.

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

Specifications Comparison			
Device	**Neurovirtual** Maxxi Flow Sensor	**S.L.P. Ltd.** Thermocouple Flow Sensor (Easy flow)	**Braebon** ULTIMA AIRFLOW SENSOR
510(k) Number	K201495	K922112	K981445
Regulation	21 CFR 868.2375	21 CFR 868.2375	21 CFR 868.2375
Classification	MNR	BZQ	BZQ
Target population	Adults	All Ages	All Ages
Environment	sleep laboratory, clinics or hospitals	sleep laboratory, clinics or hospitals	sleep laboratory, clinics or hospitals
Application	Respiratory thermocouple flow sensor	Respiratory thermocouple flow sensor	Respiratory thermocouple flow sensor
Mechanical application	Sensor is placed under the patient's nostrils	Sensor is placed under the patient's nostrils	Sensor is placed under the patient's nostrils
Structure	Thermocouple elements covered by TPC plastic injection with a wire to connect to the PSG amplifier.	Thermocouple elements covered by TPC plastic injection with a wire to connect to the PSG amplifier.	Thermocouple elements covered by TPC plastic injection with a wire to connect to the PSG amplifier.
Contact Material	Thermoplastic elastomers (TPC-ETs)	Thermoplastic elastomers (TPC-ETs)	Thermoplastic elastomers (TPC-ETs)
Wire Material	Insulated Teflon wire	Insulated Teflon wire	Insulated Teflon wire
Wire Colors	White	White	White
Connector	DIN 42-802 touch proof	DIN 42-802 touch proof	DIN 42-802 touch proof
Signal output	AC signal	AC signal	AC signal
Signal Frequency range	0-30 HZ	0-30 HZ	0-30 HZ

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Sensor Resistance	<10Ω	<10Ω	Not disclosed by manufacturer
Sensor Dimensions	032 x 1.36 x 0.23 (in)	0.30 x 1.3 x 0.22 (in)	0.30 x 1.3 x 0.22 (in)
Single-Use	No	No	No
Cable length	3ft and 7ft	3ft and 7ft	3ft and 7ft
Package	Plastic bag	Plastic bag	Plastic bag
Pictures			

Discussion: The Maxxi Flow and the predicate devices, are substantially equivalent in technology, function, and intended use, all sensors are indicated to provide respiratory airflow signal for a polysomnography device; all devices use the same method of action; all devices use equivalent material and all devices provide equivalent output signals.

I) Applied Standards:
In order to reach high quality and effectiveness the Maxxi Flow Sensor is produced in compliance with the following standards:

- ISO 13485:2003, "Medical Devices, Quality Management Systems: Requirements for Regulatory Purposes" and FDA GMP "Good Manufacturing Practices".
- ISO10993-1:2009, "Biological Evaluation of Medical Devices"
- 60601-1 3a edition - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

J) Non-clinical Testing:
The test performance comparing the Maxxi Flow and the predicate device Easy Flow manufactured by S.L.P Ltd was performed and the summary results are show in the summary below.

Test	Description	Criteria	Results
Parts Dimensions	Verify if the dimensions of the thermocouple unit are within the acceptable range and equivalent to the predicate	Allowance: +-10%	The dimensions of the thermocouple unit are within the acceptable criteria as when compared to the predicate device.
Cable Length	Verify if the wire lead 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 Flow sensor was inspected, and the result is equivalent to the predicate device.
Sensor Resistance	Verify the resistance of the sensor using the ohmmeter in a controlled test environment where the temperature is stable.	Expected: 0-10 ohms	The Maxxi Flow was inspected, and the resistance is between the acceptable criteria range. (2.0 ohms)

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Output signals Frequency and Amplitude Tests	The sensor Maxxi Flow and the predicate Easy Flow 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.

Additionally, the test performance with different environment temperatures was performed. The results showed exact same frequency as the predicate, with minimal difference on voltage amplitude and resistance measurement values.

Conclusion: The Maxxi Flow and the predicate device Easy Flow manufactured by S.L.P Ltd., are substantially equivalent in technology, function, and intended use.