April 24, 2020

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

Re: K191492
Trade/Device Name: Maxxi Position Sensor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: January 28, 2020
Received: February 3, 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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K191492

Device Name
Maxxi Position Sensor

Indications for Use *(Describe)*
The Maxxi Position Sensor is intended for use with the BWMini polysomnograph system, to acquire the body position of adult patients during sleep studies. The Sensor produces signals for five positions: standing/sitting, supine, prone, left and right. It is intended for use in research, home sleep studies, ambulatory, and clinical environments.

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 Suite #100
Fort Lauderdale, FL 33309 - USA
Phone: (786) 693-8200 – Fax (305) 393-8429

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

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

D) Contact Person: Eduardo J. Faria

E) Revision Date: March 24, 2020

F) Classification Name:
Common / Usual Name: Body Position Sensor
Proprietary Name: Maxxi Position Sensor
Product code: GWQ, OLV
Class: Class II
Regulation: 21 CFR 882.1400

G) Device Description

The Maxxi Position Sensor is a sensor that attaches to either around chest or abdominal belts using velcro tapes- so no additional belts or attachment systems are needed. The sensor features a fully encapsulated active element for trouble-free cleaning.
The Maxxi Position Sensor produces a clear and reliable signal for five positions: Upright, supine, prone, left and right.
It comes with 7ft long cable for a convenient connection with the PSG device recorder.

H) Substantial Equivalence:

The Maxxi Position Sensor is equivalent with the following products:

510(k) Number	Model	Company
K131335	BWMINI	NEUROVIRTUAL USA INC.
K981969	ULTIMA BODY POSITION SENSOR	BRAEBON MEDICAL CORP.

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1. Indications for Use:

Indications for Use Comparison		
Neurovirtual Maxxi Position Sensor	**BRAEBON MEDICAL CORP.** Ultima Body Position Sensor	**Neurovirtual BWMini**
The Maxxi Position Sensor is intended for use with the BWMini polysomnograph system, to acquire the body position of adult patients during sleep studies. The Sensor produces signals for five positions: standing/sitting, supine, prone, left and right. It is intended for use in research, home sleep studies, ambulatory, and clinical environments.	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 screenings 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.	BWMini is an electroencephalograph, which is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head. BWMini is multi-channel (up to 32 channels) system designed for Electroencephalograph (EEG), Polysomnography (PSG) and Home Sleep Testing (HST) recording application, in research, home sleep studies, ambulatory and clinical environments. The BWMini does not make any judgment of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

2. Technological Characteristics Comparison:

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

Specifications Comparison				
Device Brand and Common Name	**Neurovirtual** Maxxi Position Sensor	**Neurovirtual** BWMini	**BRAEBON MEDICAL CORP.** Ultima Body Position Sensor	**Comments**
510(k) Number	K191492	K131335	K923033	NA
Classification	GWQ, OLV	GWQ, OLV	LEL	The predicate BWMini is classified as GWQ because it is a full polysomnograph recording device that includes an internal body position sensor with same
Regulation #	21 CFR 882.1400	21 CFR 882.1400	21 CFR 882.5050	
Classification Name	Electroencephalograph used for polysomnography or sleep studies	Electroencephalograph used for polysomnography or sleep studies	Device, Sleep Assessment	

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				technological characteristics as the subject device. This information may not publicly available.
Patient Population	Adult patient	Adult patient	Adult patient	Identical
Indented Environment	The intended environments are research, home sleep studies, ambulatory, and clinical environments. It is intended for adult patients.	The intended environments are research, home sleep studies, ambulatory, and clinical environments. It is intended for adult patients.	The intended environments are research, home sleep studies, ambulatory, and clinical environments. It is intended for adult patients.	Identical
Prescription Use	YES	YES	YES	Identical
Sensor Material	Plastic ABS enclosure Electronic components Printed Circuit board	Plastic ABS enclosure Electronic components Printed Circuit board	Plastic ABS enclosure Electronic components Printed Circuit board	Equivalent
Cables Material	ABS – plastic injection	ABS – plastic injection	ABS – wire jacket	Equivalent
Interface with Patient	Around the abdomen or thorax belts using velcro tapes	Around the abdomen or thorax belts using velcro tapes	Around the abdomen or thorax belts using velcro tapes	Identical
Type of Equipment to Be Connected to	Polysomnography recorder	NA	Polysomnography recorder	Identical
Connector Type	Monopolar DIN 42-802 touch proof	NA	Monopolar DIN 42-802 touch proof	Identical
Signals output	Body position: upright, supine, prone, left and right 0 to 1 VDC output	Body position: upright, supine, prone, left and right 0 to 1 VDC output	Body position: upright, supine, prone, left and right 0 to 1 VDC output	Identical
Position Detection Technology	Combination of electronic tilt switches generates different types of signals depending of the sensor position.	Combination of electronic tilt switches generates different types of signals depending of the sensor position.	Combination of electronic tilt switches generates different types of signals depending of the sensor position.	Identical

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Power Source	3VDC coin battery	AA batteries	3VDC coin battery	Similar
Applicable Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Identical
Packing	Plastic bag	Cartoon box	Plastic bag	Equivalent
Sensor Dimensions	39x31x15 mm	NA	40x29x14 mm	Equivalent
Device Picture				Equivalent

Substantial Equivalency Discussion: The Maxxi Position and the predicate devices BWMini and Ultima Body Position Sensor are substantially equivalent in technology, function, and intended use: the devices are intended to provide body position signals for sleep disordered studies; the devices use the same method of action; the devices use equivalent material and also provide identical output signals.

I) Performance Testing Summary:

1. Electrical Safety and Effectiveness Testing

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

2. EMC Testing

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

3. Signal Quality and Comparison Testing:

Signal integrity tests were conducted for the Maxxi Position 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 Ultima Body Position Sensor.

4. Performance Testing:

The performance test was conducted in order to verify technological and functional performance characteristics when compared with the predicate. The summary of the results is listed below.

Performance Test	Description	Acceptance Criteria (Predicate Specs)	Maxxi Position Results
Sensor Dimensions	Verify if the dimensions of the sensor are within the acceptable range in accordance with the product specifications.	40x29x14 mm Allowance: +-10%	Measured Value: 39x31x15 mm Pass (x) Fail ( )

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Cable Dimensions	Verify if the cable length is within the acceptable range.	Cable length: 7ft Allowance: +-5%	Measured Value: 7ft Pass (x) Fail ( )
Cable Connectivity	Using a multimeter in continuity scale, check if the internal belt wiring has connectivity.	Not allowed false contact, or no connectivity.	Pass (x) Fail ( )
Sensor Visual Aspects	Verify the visual aspects of the product including, labeling, mechanism of action, method of connection, application, interaction with the user and cable specifications.	The visual aspects of the Maxxi Position must be similar/equivalent to the predicate device Ultima Body Position Sensor.	Pass (x) Fail ( )
Sensor Signal Aspect	Signal integrity tests were conducted for the Maxxi Position 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 Ultima Body Position Sensor.	Qualitative signal analysis must be similar in signal type, amplitude and linearity when compared with the predicate device Ultima Body Position Sensor.	Pass (x) Fail ( )
Sensor Functional Aspect	Verify if the PSG system identifies the sensor's position Supine, Prone, Left, Right and Stand accordingly with the respective sensor output signals.	All positions signal shown in the user manual must follow the patient body position based on the sensor axis position	Pass (x) Fail ( )

5. Performance Testing in Simulated Use:

A comparative test in simulated use was performed in N=20 volunteers in a simulated use study between the subject device and predicates in order to compare the accuracy and latency to detect the patient's body position in a PSG system.

The results showed the average time to detect the patient body position was 1 second of latency difference between the devices and 100% of accuracy between them. This result demonstrated substantially equivalence between the subject device and the predicates.

Conclusion: Based on the substantial equivalence comparison, and nonclinical performance tests applied to the Maxxi Position Sensor and the predicates, we conclude that the devices have similar indications for use, technological characteristics and method of action, additionally the nonclinical performance testing demonstrate that the subject device is safe and effectively as well substantially equivalency to the predicates.

J) Clinical Testing:

No clinical trial was performed.