DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2015

Neurovirtual USA, Inc.
Eduardo Faria, CEO
2315 NW 107th Avenue
Suite 1M27
Doral, FL 33172

Re: K131335
Trade/Device Name: BWMini EEG (Model PV 2310), BWMini HST (Model PV 2312), BWMini PSG (Model PV 2311)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Codes: GWQ, OLV
Dated: December 29, 2014
Received: December 31, 2014

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -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

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)*
K131335

Device Name
BWMini (EEG, HST and PSG)

Indications for Use *(Describe)*
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.

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."

Section 5

510(k) SUMMARY

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

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

B) Address: 2315 NW 107th Ave – Suite 1M27
Doral, FL – 33172

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

D) Contact Person: Eduardo J. Faria

E) Preparation Date: January 26, 2015

F) Classification Name:
Common / Usual Name: Full-Montage Standard Electroencephalograph
Proprietary Name: BWMini (EEG, HST, PSG)
Product Code: GWQ
Additional Product Codes: OLV
Classification: Class II
Regulation Number: 21 CFR 882.1400

G) Substantial Equivalence:

The BWMini is equivalent with the following products:

510(k) Number	Model	Company
K042150	XLTEK Trex	EXCEL TECH. LTD.
K946094	CADWELL EASY AMBULATORY EEG	CADWELL LABORATORIES, INC.

Technological Characteristics Comparison:

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

	Neurovirtual BWMini	**CADWELL EASY AMBULATORY EEG**	**XLTEK Trex**	**Analysis of Differences**
510(k) Number	K131335	K946094	K042150	NA
Classification	GWQ	GWQ	GWQ	NA
Indication of Use	EEG, PSG and HST	EEG, PSG and HST	EEG, PSG and HST	NA
Number of Channels	Up to 32	Up to 32	Up to 32	NA
Data Storage	Memory Card	Memory Card	Memory Card	NA
Software Based	Windows	Windows	Windows	NA
Material (External)	Hard Plastic	Hard Plastic	Hard Plastic	NA
Power Source	Batteries	Batteries	Batteries	NA
AD Resolution	16 Bits	16 Bits	12 Bits	Our product uses the most current processors that exceed the minimum resolution requirement for recording EEG according to the ACNS (American Clinical Neurophysiology Society) Guideline.
Notch Filter	50-60Hz	50-60Hz	50-60Hz	NA
Sensitivity Selection	1-500uv/mm Configurable	1-100uv/mm Configurable	1-200uv/mm Configurable	Our product exceeds the sensitive range requirement for recording EEG according to the ACNS (American Clinical Neurophysiology Society) Guideline.
Low Frequency filters	0.16 – 15Hz Configurable	0.02-15 Hz Configurable	0.25 – 15Hz Configurable	Our product exceeds the Low Frequency Filters requirement for recording EEG according to the ACNS (American Clinical Neurophysiology Society) Guideline.
High Frequency filters	15 – 100 Hz Configurable	15 - 100 Hz Configurable	15 – 100Hz Configurable	NA
Auxiliary DC Inputs	2 DC Inputs	1 DC Input	4 DC Inputs	DC Channels are not a requirement by the ACNS Guideline for recording EEG.
User Interface	IBM PC	IBM PC	IBM PC	NA
Software	BWAnalysis 510(k)K062533	EasyWrite and Easy Reader 510(k)K932507	Excel Neuroworks 510(k)K980214	This is only a Commercial Name for each manufacturer Software

Conclusion: As showed above the comparison shows that BWMini was developed to be substantial equivalent to the predicates, not raising any safety or effectiveness concerns.

H) Intended Use:

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.

Neurovirtual BWMini	**CADWELL EASY AMBULATORY EEG**	**XLTEK Trex**
BWMini is inteded to be used as: -Electroencephalograph(EEG) -Polysomnography (PSG) -Home Sleep Testing (HST) BWMini can be used in research, home sleep studies, ambulatory and clinical environments.	Easy Ambulatory EEG is inteded to be used as: -Electroencephalograph(EEG) -Polysomnography (PSG) -Home Sleep Testing (HST) Easy Ambulatory EEG can be used in research, home sleep studies, ambulatory and clinical environments.	XLTEK Trex is inteded to be used as: -Electroencephalograph(EEG) -Polysomnography (PSG) -Home Sleep Testing (HST) XLTEK Trex can be used in research, home sleep studies, ambulatory and clinical environments.

I) Safety and Effectiveness:

The BWMini is in compliance with the applicable clauses of the following standards:

- IEC 60601-1:2005, "Medical Device Equipment: General Requirements for Safety"

- IEC 60601-1-1:2009, Medical electrical equipment - Part 1: General requirements for safety - Section 1: Collateral standard: Safety requirements for medical electrical systems

- IEC 60601-1-2:2008, "Medical Device Equipment – General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility, Requirements and Test"

- IEC 60601-2-26:2002, "Medical Device Equipment – Particular requirements for the safety of electroencephalographs"

- IEC 60601-1-4:2009, "Medical Device Equipment – General Requirement for Safety, Collateral Standard: Programmable Electrical Medical Systems"

- EN ISO 14971:2007, "Medical Devices: Application of Risk Management to Medical Devices"

- EN ISO 13485:2003, "Medical Devices, Quality Management Systems: Requirements for Regulatory Purposes"

- General Principles of Software Validation: FDA Guidance software validation version 1.1 (June 09, 1997)

Conclusion:

The BWMini is an EEG, PSG and HST recording device that is safe, effective and equivalent to the predicates above.

J) Non-clinical Testing:

The principal EEG authors speak about an acceptable frequency between 0.5Hz to 100Hz.

We test the produced units for performance of the device on the following frequencies: 0.5Hz, 1Hz, 2Hz, 3Hz, 4Hz, 5Hz, 10Hz, 15Hz, 20Hz, 25Hz, 30Hz, 40Hz, 50Hz, 70Hz, 80Hz, 90Hz, and 100Hz, comparing the results with a known and calibrated external source. A deviation of +/- 5% in the injected value in each frequency is acceptable.

The complete test report as **ATTACHMENT 7.**

Conclusion

The BWMini meets the performance standards for perform EEG and PSG exams.