OCT 2 8 2011

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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: September 28, 2011

F) Classification Name:
Common / Usual Name: Full-Montage Standard Electroencephalograph
Proprietary Name: BWIII (Models: EEG, EEG Plus, PSG and PSG Plus)
Product Code: GWQ
Additional Product Codes: OLV
Class: Class II
Regulation: 882.1400

G) Substantial Equivalence:

The BWIII is equivalent with the following products:

510(k) Number	Model	Company
K932407	Easy Write and Easy Reader	Cadwell Laboratories, Inc.
K991900	XLTEC PSG-40 Polysomnography	Excel Tech Ltd.
K062533	BWII Digital	Neurovirtual USA Inc.

Technological Characteristics:

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

	Neurovirtual BWIII				Neurovirtual BWII		Cadwell Easy Write		Excel Tech PSG-40
Model	EEG	EEG Plus	PSG	PSG Plus	EEG	PSG	Easy II EEG	Easy II Sleep	Connex
510(k) Number	K062533						K932407		K991900
Classification	GWQ				GWQ		GWQ		GWQ
Application	EEG	EEG	PSG	EEG and PSG	EEG	PSG	EEG	EEG and PSG	EEG and PSG
Number of Channels	31	47	29	50	25	29	25	32	Up to 50
Oximeter	Built-in				Built-in		Built-in		Built-in
Flash Stimulator	1-30 Hz				1-30 Hz		1-25 Hz		1-30 Hz
Data Communication	Ethernet / RJ-45				Ethernet / RJ-45		Ethernet / RJ-45		Ethernet / RJ-45
Software Based	MS Windows				MS Windows		MS Windows		MS Windows
Material (External)	Hard Plastic				Hard Plastic		Hard Plastic		Hard Plastic
Power Source	External				External		External		Internal
Line Power	100-240VAC				127-220VAC		120/250VAC		130/215VAC
AD Resolution	16 Bits				12 Bits		16 Bits		12 Bits
Common Mode Rejection Ratio	50-60Hz				50-60Hz		50-60Hz		60Hz
Sensitivity Selection	1-500uv/mm				1-500uv/mm		1-100uv/mm		1-200uv/mm
Low Frequency filters	0.16 – 10Hz				0.16 – 10Hz		0.02-10 Hz		0.25 – 20Hz
High Frequency filters	15 – 100 Hz				15 – 70 Hz		15 - 100 Hz		15 – 120Hz
Auxiliary DC Inputs	4	4	8	8	1	3	1-6 DC Inputs		1-6 DC Inputs
User Interface	IBM PC				IBM PC		IBM PC		IBM PC
Software	BWAnalysis 510(k)K062533				BWAnalysis 510(k)K062533		EasyWrite and Easy Reader 510(k)K932507		Excel Neuroworks 510(k)K980214

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H) Description:

BWIII is multi-channel (up to 50 channels) system designed for polysomnography (PSG) and electroencephalograph (EEG) recording application, in sleep lab, hospital or clinical environment under the supervision of a physician, using a laptop or a desktop computer.

The BWIII system consists of four major components: the amplifier unit, head box unit, flash stimulator unit and the power module (all plastic made). The system provides connections for electrodes and sensors, and connects to the computer using an ethernet cable.

The BWIII works with any good quality patient leads / electrodes and sensors snore, flow, effort belts and position) that have the safety touch connectors and are legally marketed in accordance with FDA requirements. As these accessories are already legally in the market from different manufactures, they are not part of this submission.

The BWIII 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.

I) Intended Used:

The BWIII system may be used for electroencephalography (EEG) and sleep recordings (polysomnography) in research and clinical environments. It acquires displays and archives EEG and PSG data for on-screen review, annotation, and event-marking by the user.

The BWIII requires competent user input, and its output must be reviewed and interpreted by a trained physician who will exercise professional judgment in using this information.

The BWIII 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.

J) Safety and Effectiveness:

The BWIII 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)

K) Non-clinical Testing:

In order to demonstrate that the use of EEG / PSG equipment is safe and effective, we have compiled one article from the Journal of Epilepsy and Clinical Neurophysiology (J Epilepsy Clin Neurophysiol 2004; 10(4):191-200) that demonstrates the safety and effectiveness regarding the equipment.

The full article "*Nonconvulsive Status Epilepticus: Clinical and Electrographic Aspects*" is attached on the **ATTACHMENT 05.**

L) Conclusion

The BWIII system is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 28 2011

Neurovirtual USA, Inc.
c/o Mr. Eduardo Faria
President
2315 NW 107th Avenue, Ste. 1M27
Doral, FL 33172

Re: K112107
Trade/Device Name: BWIII EEG, BWIII EEG Plus, BWIII PSG, BWIII PSG Plus
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: September 28, 2011
Received: October 4, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112107

Device Name: BWIII

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112107