DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 11, 2017

Neurovirtual USA, Inc.
Eduardo Faria
CEO
2315 NW 107th Ave
Suite #1M27
Doral, Florida 33172

Re: K163547
Trade/Device Name: MaxxiGold Electrode 48", MaxxiGold Electrode 60", MaxxiGold Electrode 96"
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 4, 2017
Received: April 7, 2017

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" (21 CFR 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,

Michael J. Hoffmann -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

Enclosure

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)*
K163547

Device Name
MaxxiGold Electrode 48", MaxxiGold Electrode 60", MaxxiGold Electrode 96"

Indications for Use *(Describe)*
The MaxxiGold Electrode is intended for non-invasive use as recording electrodes in studies of physiological signals. These devices are indicated for use with adult or pediatric patients during electroencephalography, including biofeedback, sleep studies and evoked potential recordings.

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.

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Neurovirtual USA Inc.
2315 NW 107th Ave 1M27
Doral, FL 33172 - 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: 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: April 4, 2017

F) Classification Name:
Common / Usual Name: Cutaneous Electrode
Proprietary Name: MaxxiGold Electrode
Product Code: GXY
Class: Class II
Regulation: 21 CFR 882.1320

G) Device Description

MAXXIGOLD Electrode is intended for non-invasive use as recording electrodes in studies of physiological signals. These devices are indicated for use with adult or pediatric patients during electroencephalography, including biofeedback, sleep studies and evoked potential recordings.
The product is offered in 3 different length sizes, 48", 60" or 96".
The product is offered in package of 5 or 10 units, with multicolor wires.
The electrode is compatible with any recording device with the DIN 42-802 receptacle which is the gold standard for EEG and EMG recording machines.

H) Substantial Equivalence:

The MaxxiGold Electrode is equivalent with the following products:

510(k) Number	Model	Company
KO22197	Surface Electrode for Electroencephalography	The Electrode Store, Inc.
K071118	EEG Surface Electrode System	Ives EEG Solutions, Inc

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1. Intentions for Use:

The MaxxiGold Electrode is a cutaneous electrode device intended for medical purposes, such as to acquire biological signals and conduct this signal to a recoding machine.

Intention of Use Comparison		
Neurovirtual MaxxiGold Electrode	**The Electrode Store, Inc.** Surface Electrode for Electroencephalography	**Ives EEG Solutions, Inc** EEG Surface Electrode System
The MaxxiGold Electrode is intended for non-invasive use as recording electrodes in studies of physiological signals. These devices are indicated for use with adult or pediatric patients during electroencephalography, including biofeedback, sleep studies and evoked potential recordings.	The Surface Electrode for Electroencephalography is intended for non-invasive use as recording electrodes in studies of physiological signals. These devices are indicated for use with adult or pediatric patients during electroencephalography, including biofeedback, sleep studies and evoked potential recordings.	The EEG Surface Electrode System is intended for non-invasive use as recording electrodes in studies of physiological signals. These devices are indicated for use with adult or pediatric patients during electroencephalography, including biofeedback, sleep studies and evoked potential recordings.

2. Technological Characteristics Comparison:

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

Specifications Comparison			
Device	**Neurovirtual** MaxxiGold Electrode	**The Electrode Store, Inc.** Surface Electrode for Electroencephalography	**Ives EEG Solutions, Inc** EEG Surface Electrode System
510(k) Number	K163547	KO22197	K071118
Classification	GXY	GXY	GXY
Application	Electrode cutaneous	Electrode cutaneous	Electrode cutaneous
Contact design	Metallic Disk Plate	Metallic Disk Plate	Metallic Disk Plate
Structure	Metallic Disk Plate connected to a lead wire and terminate in a DIN touch proof connector.	Metallic Disk Plate connected to a lead wire and terminate in a DIN touch proof connector.	Metallic Disk Plate connected to a lead wire and terminate in a DIN touch proof connector.
Contact Disk Material	Gold plated	Gold plated	Gold plated
Wire Material	Insulated Teflon wire	Insulated Teflon wire	Insulated Teflon wire
Wire Colors	Multicolor	Multicolor	Multicolor
Joint material	Heat shrink tube	Heat shrink tube	Heat shrink tube
Connector	Monopolar DIN 42-802 touch proof	Monopolar DIN 42-802 touch proof	Monopolar DIN 42-802 touch proof
Package	Plastic bag	Plastic bag	Plastic bag

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

I) Safety and Effectiveness:

In order to reach high quality and effectiveness the MaxxiGold Electrode 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".

J) Non-clinical Testing:

No clinical trial was performed.