K131882

FEB 12 2014

510(k) Summary

Contact Details

Applicant Name: Electrical Geodesics, Inc.
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541-687-7962

Contact Name: Linda J. Bovard
Bovard Consulting LLC
29611 Simmons Road, Eugene, OR 97405

Date Prepared: February 11, 2014

Device Name

Trade Name: Geodesic EEG System™ 400 Series

Common Name: Electroencephalograph

Classification Name: Electroencephalograph, 882.1400, primary code OLT Non-normalizing quantitative electroencephalograph, secondary code GWQ electroencephalograph

Legally Marketed Predicate Device(s)

K063797 Geodesic EEG System™ 300 (GES 300) by Electrical Geodesics, Inc.

Device Description

The Geodesic EEG System™ 400 Series (GES 400) is a digital electroencephalograph system (EEG). Each system consists of an amplifier, central processing unit, software, electrodes, and components of a standard personal computer (monitor, keyboard, and mouse).

The GES 400 Series consists of 3 models (GES 400, GES 405, and GES 410), each of which has a slightly different amplifier. The amplifiers are very similar and all are called Net Amps™. They vary in connectors used to attach the electrodes and in the A/D chips, which support different maximum sampling rates. The other parts of the GES 400 Series are identical and consist of an isolation transformer, a power supply, Net Station software, proprietary EEG electrodes, and data acquisition computer. Optional accessories include a cart that holds the components of the system, interface cable, and articulated arm. The GES 400 Series also accepts third party DIN 42802 electrodes and an SpO_2 electrode.

Intended Use/Indications for use

The Geodesic EEG System 400 Series™ (GES 400) is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Substantial Equivalence Comparison

The GES 400 Series is a modification to the Geodesic EEG System™ 300. In the charts below, the column labeled GES 400 gives a full description for comparison with the predicate device, GES 300. "Same" in the GES 405 and GES 410 columns means that this item is identical to the GES 400.

Table 1: Overall Comparison

Comparison	GES 400 Series			GES 300
	GES 400	GES 405	GES 410	K063797
System components:				
amplifier	Net Amps™ 400	Net Amps™ 405	Net Amps™ 410	Net Amps™ 300
CPU	Intel based	Same	Same	Intel based
preferred electrodes	HCGSN	Same	Same	HCGSN
electrode connector	Hypertronics	GEM	Hypertronics	Hypertronics
other supported EEG electrodes	None	Same	Same	None
other supported electrodes	Yes – DIN 42802	Same	Same	Yes – DIN 42802
acquisition software	Yes – Net Station® 4.5	Same	Same	Yes – Net Station® 4.2
diagnostic software	No	Same	Same	No

The overall features of the GES 400 Series and the GES 300 are very similar. They have the same basic components and accept the same electrode types. The software has been upgraded from Net Station 4.2 to Net Station 4.5. There are three models of amplifier, which lead to the three models in the GES 400 Series. These amplifiers are described more fully in Table 2. As noted in Table 1, the Net Amps 400 and Net Amps 410 accept HCGSN electrodes with a Hypertronics connector, just like the GES 300. The Net Amps 405 accepts HCGSN electrodes with a GEM connector, which was cleared with the Geodesic EEG System Mobile (GEM) under K 112353. The electrodes used with all models are identical.

In overall features the GES 400, GES 405 and GES 410 are substantially equivalent to the GES 300.

Table 2: Amplifier Comparison

Comparison	GES 400 Series			GES 300
	GES 400	GES 405	GES 410	K063797
Amplifier designation	Net Amps 400	Net Amps 405	Net Amps 410	Net Amps 300
Number of channels	Up to 256	Up to 32	Up to 256	Up to 256
A/D conversion	24 bit	Same	Same	24 bit
Sampling rate	8,000 Hz	8,000 Hz	20,000 Hz	Up to 20,000 Hz
Sample and hold	Yes	Same	Same	Yes
Sensitivity - digitization precision - display sensitivity	 0.024 μV/bit selectable	 Same Same	 Same Same	 0.024 μV/bit selectable
High and low pass filters	Fully selectable in software.	Same	Same	Fully selectable in software.
Notch filter	50 Hz and 60 Hz in software	Same	Same	50 Hz and 60 Hz in software
Input impedance	>1.0 GΩ	Same	Same	>200 MΩ
CMRR	>90dB 50/60 Hz	Same	Same	90dB 50/60 Hz
Noise level	0.7 μV RMS (1.4 μV peak-to-peak)	Same	Same	0.7 μV RMS (1.4 μV peak-to-peak)
Digital interface	Ethernet	Same	Same	FireWire
Processor	Embedded Atom processor	Same	Same	Embedded Mindready processor
Fully software controlled	Yes	Same	Same	Yes
Power supply	100-240 VAC, 50/60 Hz, 1.0 A	Same	Same	100-240 VAC, 50/60 Hz, 1.0 A

Both the Net Amps 400 Series and the Net Amps 300 are very similar. The Net Amps 400 and 410 accept the same number of channels as the Net Amps 300. Because the Net Amps 405 accepts only the GEM connector the maximum number of channels is 32. The sampling rate varies in the Net Amps 400 series, though the sampling rate in the Net Amps 410 is identical to the Net Amps 300. The input impedance of all the Net Amps 400 models has been improved with respect to the Net Amps 300. The digital interface and the embedded processor have changed from the Net Amps 300. Both of these hardware changes are upgrades to widely used current technologies. All other amplifier features are the same. None of the differences between the Net Amps 400 Series amplifiers and the Net Amps 300 raise new issues of safety and effectiveness.

Testing

Electrical safety and electromagnetic interference testing have been conducted to UL 60601-1, IEC 60601-1-2, IEC 60601-2-26, CAN/CSA 601.1-M90, and CAN/CSA 60601-2-26. Additional standards used in the development of the product were EN 62304 and EN 62366. Verification and validation testing of the software has also been conducted.

No animal or clinical testing was submitted.

Conclusion

The Geodesic EEG System™ 400 Series (GES 400) is substantially equivalent to the Geodesic EEG System™ 300 (GES 300) based on intended use and device features.

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 12, 2014

Electrical Geodesics, Inc.
c/o Ms. Linda J. Bovard, RAC
Bovard Consulting LLC
29611 Simmons Road
Eugene, OR 97405

Re: K131882
Trade/Device Name: Geodesic EEG System 400 Series (GES 400)
Regulation Number: 21 CFR 882.1400
Regulation Name: Non-normalizing quantitative electroencephalograph software
Regulatory Class: Class II
Product Code: OLT
Additional Product Codes: GWQ
Dated: December 23, 2013
Received: December 27, 2013

Dear Ms. Linda J. Bovard:

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 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. 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,

Carlos L. Peña-S

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 on last page.

510(k) Number *(if known)*
K131882

Device Name
Geodesic EEG System 400 Series (GES 400)

Indications for Use *(Describe)*

The Geodesic EEG System 400 Series (GES 400) is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos Pena -S

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