K112353

FEB 17 2012

510(k) Summary

Contact Details

Applicant Name: Electrical Geodesics, Inc.

Address: 1600 Millrace Drive, Suite 307, Eugene, OR 97403
Phone: 541-687-7962
Fax: 541-687-7963

Contact: Linda Bovard
Bovard Consulting LLC
29611 Simmons Road, Eugene, OR 97405
541-345-5431

Date Prepared: November 17, 2011

Device Name

Trade Name: Geodesic EEG Mobile 100 (GEM 100)

Common Name: EEG

Classification Name: Electroencephalograph, 882.1400, GWQ

Legally Marketed Predicate Device(s)

K033399, GWQ, Geodesic EEG System 100, Model 120, Electrical Geodesics, Inc.

Device Description

The Geodesic EEG Mobile 100 (GEM 100) is a digital electroencephalograph system (EEG). It consists of an amplifier, two adapters, central processing unit, software, electrodes, isolation transformer, and components of a standard personal computer (monitor, keyboard, and mouse). Integral components allow wireless communication.

The GEM 100 has 4 configurations. These are based on the type of EEG electrodes that will be used and the environment for use. The Neurotravel software is used to acquire, record, and archive the data from all 4 configurations. These configurations are:

- Ambulatory EEG only
- Ambulatory EEG with conventional electrodes and physiological sensors
- Stationary (in-clinic) EEG only
- Stationary (in-clinic) EEG with conventional electrodes and physiological sensors

The GEM 100 EEG Amplifier is used with all configurations, but the other components vary depending on the requirements of the patient and physician. Accessories that can be used with the GEM 100 include: Sensor Kit for SpO2, LTM Net Support Kit, Video EEG, photic stimulator, TTL patient event switch, laser or inkjet printer, mobile cart, and ambulatory pouch.

The GEM 100 operates like other digital electroencephalographs. It can run on mains power or on battery power. Data can be recorded to a CompactFlash card or to the system computer. Data can be transmitted by USB connection or by Bluetooth or can be transferred from the Compact Flash card to the system computer.

Intended Use/Indications for use

The Geodesic EEG Mobile (GEM 100) 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 Geodesic EEG Mobile 100 (GEM 100) is a modification to the Geodesic EEG System 100, Model 120, which was submitted by Electrical Geodesics, Inc. and cleared for marketing under K033399 on August 4, 2004. There are no changes that affect intended use or fundamental scientific technologies. Parameters shown for Model 120 are those originally cleared.

Category	**GEM 100**	**Model 120 K033399**
System components:		
amplifier	Yes – Neurotravel SMART	Yes – Neurotravel WIDE
CPU	Yes – PC based	Yes – PC based
headbox	Yes – for some uses	Yes
adaptor	Yes – for some uses	No
data recording media	Yes	Yes
preferred electrodes	HCGSN GEM	Geodesic Sensor Net® 200 or 300 or HCGSN
electrolyte	KCl solution or Elefix	KCl solution
acquisition software	Yes – Neurotravel Win for PC	Yes – Neurotravel Win for PC
diagnostic software	No	No
Other supported EEG electrodes	Standard EEG electrodes	Standard EEG electrodes and cap-type electrodes

Category	GEM 100	Model 120 K033399
Other supported sensors	Standard 1.5mm safety plug passive sensors Nonin 8000AA SpO2 sensor	Standard 1.5mm safety plug passive sensors Nonin SpO2 sensors
Intended environment	Healthcare facilities and ambulatory settings	Healthcare facilities
Intended user	EEG technician or physician	EEG technician or physician
Mode of operation	Microprocessor based unit which records patient data	Microprocessor based unit which records patient data
Energy source	Mains power or battery power	Mains power
Standard number of channels	32 channels	32 channels

Non-clinical Testing

Extensive testing was conducted. The product passed general testing to IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-2-26. Additional testing was conducted to verify long term monitoring capabilities and use of an SpO2 sensor. Software verification and validation activities were also successfully completed.

Clinical Testing

No clinical testing was submitted.

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

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

FEB 17 2012

Re: K112353
Trade/Device Name: Geodesic EEG Mobile 100 (GEM 100)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: November 17, 2011
Received: November 18, 2011

Dear Ms. 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 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): K112353

Device Name: Geodesic EEG Mobile 100 (GEM 100)

Indications for Use:

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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)

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

510(k) Number K112353