K092844

GeoSource
510(k) Notification

510(k) SUMMARY

DEC 2 1 2010

Submitter's name: Electrical Geodesics, Inc.
1600 Millrace Drive, Suite 307, Eugene, OR 97403

Contact name and address: Paul Holman
Electrical Geodesics, Inc.
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Date summary prepared: 12/21/10

Device name:

Proprietary name:	GeoSource
Common or usual name:	Electroencephalograph software
Classification name:	Electroencephalograph, Class II, 882.1400 84 OLX, Source Localization Software for Electroencephalograph or Magnetoencephalograph

Legally marketed devices for substantial equivalence comparison:

510(k) Number	Product Code	Trade Name	Manufacturer
K002631	GWQ 882.1400	Electroencephalograph Software eemagine EEG	eemagine Medical Imaging Solutions GmbH
K001781	GWQ 882.1400	CURRY Multimodal Neuroimaging Software	Neurosoft, Inc.

Description of the device:

GeoSource is an add-on software module to EGI's Net Station software and can only be used on EEG data generated by EGI hardware. It runs on a personal computer. It is used to approximate source localization of EEG signals and visualize those estimated locations. It uses the linear inverse methods LORETA, LAURA, and sLORETA and the sphere and Finite Difference forward head models.

Intended use of device:

GeoSource is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects at least 3 years of age for the visualization of human brain function by fusing a variety of EEG information with rendered images of an idealized head model and an idealized MRI image.

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Technological characteristics:

Characteristic	GeoSource K092844	Electroencephalograph Software eemagine EEG K002631	CURRY Multimodal Neuroimaging Software K001781
Software only product?	Yes	Yes	Yes
EEG system	Geodesic EEG System using Net Station	Variety of systems	Variety of systems
Computer OS	Mac OS	MS-Windows based	MS-Windows XP based
Method of calculation	Idealized head model (average)	Idealized head model (average)	Idealized head model (average) Individualized head model
Method of display	Idealized MRI (average)	Idealized MRI (average)	Idealized MRI (average)
Source estimate methods:			
Dipole fit	No	Yes	Yes
Linear inverse methods	LORETA, LAURA, sLORETA	No	LORETA
Forward head models	Sphere Finite Difference Model (FDM)	Boundary Element Model (BEM)	Sphere Boundary Element Model (BEM) Finite Element Model (FEM)

Both GeoSource and CURRY use the LORETA linear inverse method and sphere head models. These were demonstrated to be substantially equivalent. Then a retrospective clinical study was done to show that the other linear inverse methods and head models gave similar results. Therefore, the linear inverse methods and forward head models have been shown to be substantially equivalent.

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Non-clinical testing conducted:

Software verification and validation testing has been conducted. This includes verification of the algorithms and checks of accuracy.

Clinical testing:

In order to compare the source localization accuracy of the GeoSource as compared to that of the predicate device, a retrospective data analysis of 20 epilepsy subjects aged 3 to 55 who had previously undergone resection surgery was provided. The analysis compared the source localization accuracy of the GeoSource software algorithms (i.e., LORETA, sLORETA, and LAURA with the GeoSource finite difference model [FDM]) to that of the predicate algorithm (i.e., LORETA using a spherical head model). All subjects had previously undergone high density (> 128 electrodes) EEG analysis prior to resection surgery, had operative data available that described the resected zone, and were determined to be Engel 1 or 2 postoperatively. The study included subjects with temporal and extra-temporal resected zones.

Each subject's EEG data was reviewed by a clinical neurophysiologist who identified spikes within the EEG. Spikes were then grouped according to topographic distribution and then averaged relative to the peak of the spike to increase the signal-to-noise ratio. The average of this dominant group was used in the source estimate. The time point used in the source estimate was the rising slope of the spike. The data were then run through the GeoSource software algorithms (i.e., LORETA, sLORETA, and LAURA with the GeoSource finite difference model [FDM]) and the predicate algorithm (i.e., LORETA using a spherical head model).

Three experienced epileptologists from the University of Washington's Regional Epilepsy Center were provided the source localization results along with summaries of the post-operative reports and asked to rate whether each of the four algorithm solutions (i.e., LORETA, sLORETA, and LAURA with the GeoSource finite difference model [FDM] and the LORETA using a spherical head model) were located within the resected brain regions. The results demonstrated that the proposed GeoSource algorithms were substantially equivalent to the predicate device algorithm.

Conclusions:

The conclusions drawn from the non-clinical and clinical tests demonstrate that GeoSource is as safe and effective as the predicate devices, Electroencephalograph Software eemagine EEG and CURRY Multimodal Neuroimaging Software.

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 Mr. Paul Holman
600 Millrace Dr. Suite #307
Eugene, OR 97403

DEC 21 2010

Re: K092844
Trade/Device Name: GeoSource
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph (EEG)
Regulatory Class: Class II
Product Code: OLX
Dated: November 16, 2010
Received: November 19, 2010

Dear Mr. Holman:

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): K092844

Device Name: GeoSource

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K092844