2.3. 510(K) Summary of Safety and Effectiveness

Submitter

CTF Systems Inc.
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Port Coquitlam, BC V3C 1M9 CANADA

Company Contact

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Regulatory Identification

Device Name: CTF Whole-Cortex MEG System

Model Names: Omega 151, Omega 275
Device Classification Name: Electroencephalograph
Device Class: II
Regulation Number: CFR 882.1400
Panel: Neurology (84)
Product Code: OLX, OLY
Classification Advisory Committee: Neurology
Establishment Registration Number (Owner/Operator): 9034609

Predicate Device Information

CTF Systems Inc. Whole-Cortex MEG System as cleared by K971329

Device Description

The Omega Whole-Cortex MEG Systems integrate up to 307 dc-SQUID axial gradiometers with workstation computers and data acquisition software in order to measure the magnetic signals generated by intercellular dendritic currents. These detectors positioned in a helmet shaped array gives the user the ability to record electrical activity of the entire surface of the brain simultaneously without having to move the position of the probe.

Description of Modification

The Omega Whole-Cortex MEG System was modified to increase the number of auxiliary channels, include changes to the electronics of the device, including the software/firmware that control the operation of the electronics, and the addition of a new software operating system for the MEG System.

Indications for Use

The Omega Whole-Cortex MEG System non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, in neurosurgical planning.

Intended Use

The Omega Whole-Cortex MEG System is intended for use as a magnetoencephalographic (MEG) device, which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained physician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active tissue responsible for critical brain functions.

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

CTF Systems, Inc.
c/o Mr. Daryl Wisdahl
Director of Regulatory affairs and_ Clinical Research
15-1750 McLean Avenue
Port Coquitlam
BC V3C 1M9_ Canada

Re: K030737
Trade/Device Name: Omega Whole-Cortex MEG System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY
Dated (Date on orig SE ltr): September 10, 2003
Received (Date on orig SE ltr): September 10, 2003

APR - 9 2012

Dear Mr. Wisdahl:

This letter corrects our substantially equivalent letter of October 10, 2003.

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,

Keosia Alexander

for

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

2.2. Indications for Use Statement

510(k) Number: K030737

Device Name: Omega Whole-Cortex MEG System

Indications For Use:

The Omega Whole-Cortex MEG System non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, in neurosurgical planning.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use **OR** **Over-The-Counter USE**

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030737