K081430

JUL 2 8 2008

510(K) Summary

Elekta Neuromag Oy
Siltasaarenkatu 18-20 A
FI-00530 Helsinki, Finland
(P.O. Box 68, FI-00511 Helsinki, Finland)
Tel: +358 9 756 240 0
Fax: +358 9 756 240 11
Contact: Mrs Anne Karvinen
Date prepared: April 1, 2008

1. Trade Name: Elekta Neuromag® with internal active shielding

2. Common Name: Electroencephalograph

3. Classification Name: Electroencephalograph, product code GWQ, Regulation: 882.1400 Class of device: Class II. OLX, OLY

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : K041264, Elekta Neuromag™, manufactured by Elekta Neuromag Oy and K050035, Elekta Neuromag® with Maxwell Filter.

5. Description of device: This premarket notification represents modifications made to our current product. Internal active shielding has been added to enhance the signal to noise ratio.

6. Intended use: The Elekta Neuromag® with internal active shielding 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 clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions.

7. Indications for use: Elekta Neuromag® with active shielding 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.

8. Technological characteristics: The internal active shielding system is a magnetic shielding technique intended to be an integrated, optional part of Elekta Neuromag® magnetoencephalograph.

Technological characteristics, continued

The internal active shielding system increases the dynamic range of the magnetometers. related external magnetic interferences, by internal feedback compensation that uses the sensor array of the biomagnetometer as a zero indicator and compensation coils placed inside the magnetically shielded room to deliver a cancellation field for attenuating the interference

9. Performance: The results of laboratory, bench testing, clinical testing, and software validation activities show that the internal active shielding modification poses no new issues of safety or effectiveness, and is therefore substantially equivalent to our predicate devices.

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

Elekta Neuromag Oy
c/o Kamm & Associates
Mr. Daniel Kamm
Principal Consultant
P.O. Box 7007
Deerfield, Illinois 60015

APR – 9 2012

Re: K081430
Trade/Device Name: Elekta Neuromag® with internal active shielding
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY, GWQ
Dated (Date on orig SE ltr): June 30, 2008
Received (Date on orig SE ltr): July 3, 2008

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of July 28, 2008.

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 (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.

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,

for Kesia Alexander

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):_____.

Device Name: Elekta Neuromag® with internal active shielding

Indications For Use:

Elekta Neuromag® with active shielding 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091437