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K 041264

ELEKTA NEUROMAG OY

Dokumentnamn/Name of document
Traditional 510(k)

Utfärdare/Issuer	Ref nr/Dok nr/Ref no/Doc no	Utgåva /Edition	Sida/Page
Louise Lindblad			
Avser/Regarding		Directory	
Elekta Neuromag™			

Section 5- 510(k) Summary

As Required by 21 CFR 807.87(k)510 (k) Summary

1. Subscribers Name & Address

Elekta Neuromag Oy
Elimäenkatu 22 B, P.O. Box 68
FIN-00511 Helsinki, Finland
Tel: + 358 9 756 240 0
Fax: + 358 9 756 240 11
Contact Person for this submission: Birgitta Fagerström
Official Correspondent: Birgitta Fagerström

2. Trade Name

Elekta Neuromag™

3. Device Classification

Common Name	Product Code	Class	Regulation Number
Electroencephalograph	GWQ	II	882.1400

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
Omega Whole-Cortex MEG System	K030737

5. Other relevant submissions

Devices	510(k) #
Neuromag Vectorview	K984401

6. Device Description (for detailed description see Section "Device Description")

The Elekta Neuromag™ is an upgraded version of the currently available Neuromag Vectorview (K984401). The Elekta Neuromag™ does not change the intended use or the fundamental scientific technology of the Neuromag Vectorview.

The Elekta Neuromag™ integrates 306 sensor elements, including planar gradiometers and and magnetometers, with computers and data acquisition and data analysis software in order to measure the differences in the magnetic signals generated by the intracellular dendritic currents. These detectors are positioned in a helmet shaped array that gives the user the ability to record the electrical activity of the entire surface of the brain simultaneously without having to move the position of the measuring device.

7. Indications for use:

The Elekta Neuromag™ 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. Intended Use:

The Elekta Neuromag™ is intended for use as a magneto encephalographic (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.

9. Substantial Equivalence:

The Elekta Neuromag™ is substantially equivalent to its predicate device the Omega Whole-Cortex MEG System (K030737) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison charts provided in this 510 k submission.

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

Ms. Birgitta Fagerström
Manager, Quality and Regulatory Affairs
Elekta Neuromag Oy
Elimäenkatu 22 B, P.O. Box 68
FIN-00511 Helsinki, Finland

APR - 9 2012

Re: K041264
Trade/Device Name: Elekta Neuromag®
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY, GWQ
Dated (Date on orig SE ltr): May 12, 2004
Received (Date on orig SE ltr): May 12, 2004

Dear Ms. Fagerström:

This letter corrects our substantially equivalent letter of August 10, 2004.

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,

Kessia 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

Section 8 - Indications for Use Statement

510(k) Number	~~To be defined~~ K 041264
Device Name	Elekta Neuromag™
Indications for Use	The Elekta Neuromag 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___ OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K041264