510(K) Summary K091393.

Elekta Oy
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Contact: Mrs Anne Karvinen
Date prepared: October 23, 2010

OCT 2 6 2010

1. **Trade Name: Elekta Neuromag® with MaxFilter 2.1**

2. **Common Name: Electroencephalograph (Magnetoencephalograph)**

3. **Classification Name: Electroencephalograph, product codes OLX and OLY, Regulation: 882.1400 Class of device: Class II.**

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

5. **Description of device:** This premarket notification represents modifications made to our current product. The present device differs from the predicate device, K050035, Elekta Neuromag® with Maxwell Filter only in the following areas of functionality: Spatiotemporal interference elimination, Graphical user interface; and Offline averager. The modification also adds compatibility with internal active shielding, an interference removal method described in K081430.

6. **Intended use:** The Elekta Neuromag® with MaxFilter 2.1 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 MaxFilter 2.1 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:** MaxFilter™ is intended to be used with Elekta Neuromag® MEG products in reducing measurement artifacts.

9. **Performance:** Performance testing consisted of software validation, phantom testing and clinical testing. As compared to predicate, the Elekta Neuromag® with MaxFilter™ 2.1 modifications is within 2 mm accuracy of the source in a phantom and provided substantially equivalent measurement accuracy in a clinical study with non-moving heads.

Comparison Table

Feature	Predicate devices K050035	Modified Device MaxFilter™ 2.1
Automated detection of bad channels	Yes	Yes
Support for Internal Active Shielding (K081430)	No	Yes
Interference elimination Software shielding, interference elimination with spatial signal space separation (SSS) Interference elimination with spatiotemporal signal space separation (tSSS)	Yes No	Yes Yes
Offline averager function to process raw data files To improve user friendliness, online averager that exists already in data acquisition software, is also available in MaxFilter as offline version. No clinical utility.	No	Yes
Graphical user interface To improve user friendliness, parallel to command line user interface, also a graphical user interface is available in MaxFilter™ 2.1. Both user interfaces perform same software modules (code) of the SSS technologies. No clinical utility.	No	Yes

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 Mr. Daniel Kamm, P.E.
Kamm & Associates
8726 Ferrara Ct.
Naples, FL 34114

OCT 26 2010

Re: K091393
Trade/Device Name: Elekta Neuromag with Maxfilter
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX, OLY
Dated: July 7, 2010
Received: July 12, 2010

Dear Mr. Kamm:

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): K091393

OCT 26 2010

Device Name: Elekta Neuromag® with MaxFilter™

Indications For Use:

Elekta Neuromag® with MaxFilter™ 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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

Kristen Bowsher

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091393