Section 4 - 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
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Tel: + 358 9 756 240 0
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Contact Person for this submission: Ms Louise Lindblad, Elekta Instrument AB, P.O. Box 7593, Stockholm, Sweden S-103 93

Official Correspondent: Mr Peter Löwendahl

2. Trade Name

Elekta Neuromag with Maxwell Filter

3. Device Classification

Common Name	Classification Number	Class	Regulation Number
Electroencephalograph	GWQ	II	882.1400

4. Regulatory History (Unmodified Predicate Device)

Devices	510(k) #
Elekta Neuromag®	K041264

5. Other relevant submissions

Devices	510(k) #
Neuromag Vectorview	K984401

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

The Elekta Neuromag with Maxwell Filter adds support for separating brain signals from external disturbances and reducing measurements artifacts.

7. Indications for use:

The Elekta Neuromag® with Maxwell Filter 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® with Maxwell Filter 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.

9. Substantial Equivalence

The Elekta Neuromag® with Maxwell Filter is substantially equivalent to its predicate device the Elekta Neuromag® (K041264) 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 510k submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2005

Elekta Neuromag Oy
c/o Ms. Louise Lindblad
Elekta Instrument AB
P.O. Box 7593
Stockholm, Sweden SE-103 93

Re: K050035
Trade/Device Name: Elekta Neuromag® with Maxwell Filter
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: January 4, 2005
Received: January 7, 2005

Dear Ms. Lindblad:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 7- Indications for Use Statement

510(k) Number	~~To be defined~~ K 050035
Device Name	Elekta Neuromag® with Maxwell Filter
Indications for Use	The Elekta Neuromag® with Maxwell Filter 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_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K050035