

OCT 31 1996

K962764

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification: Class II
Magnetoencephalograph

Common/Usual Name: Magnetoencephalographic (MEG) Device

Proprietary Name: Neuromag-122

Establishment Registration: Manufacturer:
Neuromag Ltd.
P.O. Box 357
00511 Helsinki, Finland
Phone: +358-0-394 101
Fax: +358-0-3941 203
FDA Facility Registration: # 9680891

United States Representative:
Picker International, Inc.
595 Miner Road
Highland Heights, OH 44143
FDA Owner Number: #1580240

Performance Standards No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Neuromag-122 system 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.

3. Device Description

This device integrates 122 SQUID planar gradiometers with medical super-computers and data acquisition 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 which

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 probe.

4. Safety and Effectiveness

The Neuromag-122 is substantially equivalent to the Biomagnetic Technologies Magnes Single (K901215A) in safety and effectiveness. The following chart has been compiled to demonstrate Neuromag-122's substantial equivalence to this device.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	Neuromag-122	Biomagnetic Technologies Magnes Single (K901215A)
No. of SQUID detectors / channels for MEG data	122	37
No. of auxiliary channels for other types of data (e.g EEG)	166 (typically use 32 for EEG)	51
Gradiometer	Two orthogonal planar-first-order gradiometers per location	First order axial gradiometer
Intersensor spacing	43-44 mm	20 mm
Gradiometer placement	Sixty-one locations distributed across helmet-shaped lower tip of dewar. Radius of curvature of helmet is 83 mm (front-portion) and 91 mm (back-portion).	Positioned in a circular array (diameter 14.4 cm) over a concave spherical surface with a 12.2 cm radius of curvature.
Cryogen Used	Liquid Helium	Liquid Helium
Coverage	One acquisition to cover entire head	Six to ten acquisitions to cover entire head.
Gantry	Floor mounted, standard gantry tilts up to 30°. Optional gantry tilts to 45°.	Suspended from ceiling, gantry can tilt up to 45°.
Patient Position	Seated or Supine. Optional chair insert for children.	Seated or Lying on back or side.
Head Position Indicator	Available	Available

Computer	Hewlett Packard workstation with UNIX environment.	SUN workstation with the UNIX environment
Networking Capabilities	Ethernet connections to other workstations available	Ethernet connections to other workstations available
Magnetic Shielded Room Accessories	Video monitor and two-way intercom for monitoring patients.	Interior DC lights, video cameras, and two-way intercom for monitoring patients
Intended Use	<p>Based on the product literature: The Magnes Single non-invasively detects small biomagnetic signals produced by the brain and provides information about the location of electrically active nerve tissue responsible for producing these signals. The data is presented to the physicians in an MEG image, from which they may draw information about the location of critical brain functions relative to brain anatomy.</p> <p>The Neuromag-122 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 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.</p>	



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Elaine K. Keeler, Ph.D.
Picker International, Inc.
5500 Avion Park Drive
Highland Heights, Ohio 44143

APR - 9 2012

Re: K962764

Trade/Device Name: Neuromag-122
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLY, OLT
Dated (Date on orig SE ltr): October 11, 1996
Received (Date on orig SE ltr): October 15, 1996

Dear Ms. Keeler:

This letter corrects our substantially equivalent letter of October 31, 1996.

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.

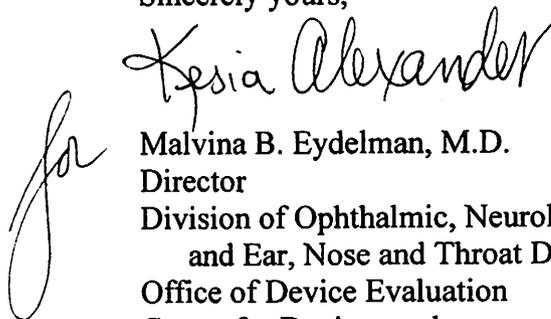
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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,

A handwritten signature in cursive script, appearing to read "Malvina B. Eydelman". To the left of the signature is a large, stylized handwritten flourish or initial, possibly "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

510(k) Number (if known): K962764

Device Name: Neuromag-122

Indications for Use:

The Neuromag-122 system 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.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

James M. Harris 10/29/96
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K962764

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

BP