DEC 30 1998 K984401

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:	Vectorview
Establishment Registration:	Manufacturer: Neuromag Ltd. P.O. Box 357 00511 Helsinki, Finland Phone: +358-9-394 101 Fax: +358-9-3941 203 FDA Facility Registration: #9680891 United States Representative: Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Neuromag Vectorview system does not change the existing intended use and indications for use for the Neuromag-122 as defined below.

The Neuromag Vectorview 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 306 sensor elements, including planar gradiometers and magnetometers, 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 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 probe.

4. Safety and Effectiveness

The Neuromag Vectorview is substantially equivalent to the Neuromag-122 in safety and effectiveness. The following chart has been compiled to demonstrate this equivalence.

Substantial Equivalence Chart

Parameter	Neuromag Vectorview	Predicate Device Neuromag-122 (K962764)
No. of SQUID sensor elements	102	61
No. of channels for MEG data	306	122
No. of auxiliary channels for other types of data (e.g EEG)	144 (typically 64 for EEG)	134 (typically use 32 for EEG)
Coil Configuration	Two orthogonal planar-first-order gradiometers and one magnetometer per location	Two orthogonal planar-first-order gradiometers per location
Intersensor spacing	34-35 mm	43-44 mm
Sensor element placement	102 locations distributed across helmet-shaped lower tip of dewar, shape based on anatomy (standard EN960:1994). Inside dimensions 222 mm (length) x 181 mm (width) x 209 mm (depth).	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).
Cryogen Used	Same.	Liquid Helium
Coverage	Same.	One acquisition to cover entire head
Gantry	Floor mounted. Dewar helmet is either tilted 30° for seated position or horizontal (180°) for supine position.	Floor mounted, standard gantry tilts up to 30°. Optional gantry tilts to 45°.

Parameter	Neuromag Vectorview	Predicate Device Neuromag-122 (K962764)
Patient Position	Same.	Seated or Supine. Optional chair insert for children.
Head Position Indicator	Same.	Available
Computer	Same.	Hewlett Packard workstation with UNIX environment.
Networking Capabilities	Same.	Ethernet connections to other workstations available
Software	Same.	Data Acquisition, Display plotting and Signal processor for continuous data.
Magnetic Shielded Room Accessories	Same.	Video monitor and two-way intercom for monitoring patients.
Intended Use & Indications for Use	Same.	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.

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. Elaine K. Keeler, Ph.D.
Manager, MR Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143

APR - 9 2012

Re: K984401
Trade/Device Name: Neuromag Vectorview
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY, GWQ
Dated (Date on orig SE ltr): December 7, 1998
Received (Date on orig SE ltr): December 9, 1998

Dear Ms. Keeler:

This letter corrects our substantially equivalent letter of December 30, 1998.

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,

Kesia 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

510(k) Number (if known): K984401

Device Name: Vectorview

Indications for Use:

The Vectorview 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)

Mark N Melkerson

for Carol (Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984401

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)