

DEC - 3 1999

K993708

SECTION 11

510(k) SUMMARY

**BIOMAGNETIC TECHNOLOGIES, INC
MAGNES® 3600 WHOLE HEAD MEG**

This 510(k) summary of safety and effectiveness for the Magnes® 3600 WH MEG is submitted in accordance with the requirements of SMDA 1990 and follows guidance from the Office of Device Evaluation concerning the organization and content of a 510(k) summary.

Applicant: Biomagnetic Technologies, Inc.
9727 Pacific Heights Blvd.
San Diego, CA 92121-3719

Address (Manufacturer): Biomagnetic Technologies, Inc.
9727 Pacific Heights Blvd.
San Diego, CA 92121-3791

Contact Person: Eugene C. Hirschhoff, Ph.D.
Vice President, Engineering
(619) 458-5617

Telephone: (619) 453-6300
(619) 453-4913 (Fax)

Preparation Date: October 1999

Device Trade Name: Magnes® 3600 Whole Head Magnetoencephalograph (MEG)

Common Name: Electroencephalograph; biomagnetometer

Classification Name: Electroencephalograph

Class: Class II

Legally marketed predicate device: Magnes® 2500 WH MEG

Description of Device: The Magnes® 3600 WH MEG consists of a magnetic sensor for detecting and measuring magnetic fields produced by the human brain, along with auxiliary equipment required to perform the measurements in a conventional medical facility environment and to display the results of the measurements to physicians in a variety of ways.

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Intended Use: The Magnes®3600 WH MEG is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity in the brain as inferred from those fields.

Performance Data: Because the specifications, performance characteristics, and intended uses of the Magnes® 3600 WH MEG are the same as the Magnes® 2500 WH MEG no performance data were required.

CONCLUSION: Based on the foregoing, Biomagnetic Technologies, Inc., believes that the Magnes® 3600 WH MEG is substantially equivalent to the Magnes® 2500 WH MEG.



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

Eugene C. Hirschkoff, Ph.D.
Vice President, Engineering
Biomagnetic Technologies, Inc.
9727 Pacific Heights Boulevard
San Diego, California 92121

APR - 9 2012

Re: K993708

Trade/Device Name: Magnes® 3600 Whole Head Magnetic Encephalograph
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX, OLY, GWQ
Dated (Date on orig SE ltr): November 2, 1999
Received (Date on orig SE ltr): November 3, 1999

Dear Mr. Hirschkoff:

This letter corrects our substantially equivalent letter of December 3, 1999.

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.

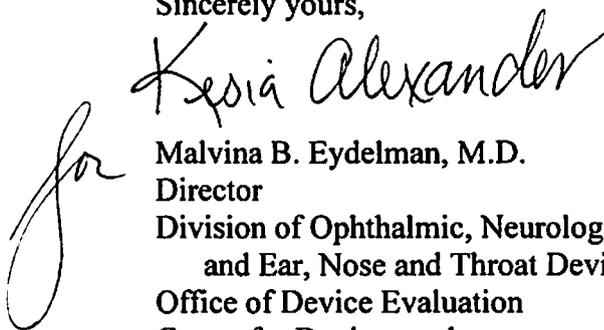
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 993708

Device Name: Magnes® 3600 Whole Head (WH) Magnetic Encephalograph (MEG)

Indications for Use Statement:

The Magnes®3600 WH MEG is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity in the brain as inferred from those fields.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

Steph Rhoads
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993708