K03 3867

DEC 1 9 2003

GE Medical Systems
General Electric Company
P.O. Box 414, Milwaukee, WI 53201

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: GE Medical Systems
PO Box 414
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Manager, Regulatory Programs

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Date Prepared: December 9, 2003

Device Name:

GE BrainWave Option(s) for MRI systems
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The GE BrainWave Option(s) for MRI systems is substantially equivalent to the currently marketed GE Functional Brain Mapping (K003947) with the main differences being that the product will be configured in several different ways, none of which include external stimulation hardware.

Device Description:

The GE BrainWave Option(s) for MRI systems is a modification to the GE Functional Brain Mapping Imaging Option for MRI systems. The GE BrainWave Option(s) produces difference images highlighting changes in blood oxygen level dependent (BOLD) images over time. These differences corresponding to changing stimuli presented to patients that are synchronized with scanning. The resulting parametric or activation images are superimposed on structural images from the same patient. The device can be used to acquire, process and display the results of BOLD (blood oxygen level dependent) MRI studies with or without external stimulation hardware.

Indications for Use:

The GE Functional Brain Mapping Option is a software and hardware package that can be used to acquire, process and display the results of BOLD (blood oxygen level dependent) MRI scan studies taken in the presence of synchronized stimuli presented to a person being scanned. When interpreted by a trained physician these results may be useful in the determination of a course of treatment.

Comparison with Predicate Device:

The GE BrainWave Option(s) for MRI systems is a modification of the GE Functional Brain Mapping Option for MRI systems, with the main difference being the various configurations that the product is marketed in.

Summary of Studies:

The GE BrainWave Option(s) for MRI systems was evaluated to the appropriate NEMA performance standards as well as the IEC 60601-1 International Medical Equipment Safety standard and IEC 60601-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. The GE BrainWave Option(s) for MRI systems is comparable to the currently marketed GE Functional Brain Mapping Option for MRI systems.

Conclusion:

It is the opinion of GE that the GE BrainWave Option(s) for MRI systems is substantially equivalent to the GE Functional Brain Mapping Option for MRI systems. Usage of the GE BrainWave Option(s) for MRI systems does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2003

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
General Electric Co.
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

Re: K033867
Trade/Device Name: GE BrainWave Option(s) for MRI Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: December 9, 2003
Received: December 12, 2003

Dear Dr. Kroger:

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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

GE Medical Systems
General Electric Company
P.O. Box 414, Milwaukee, WI 53201

STATEMENT OF INTENDED USE

510(k) Number (if known): K033867

Device Name: **GE BrainWave Option(s) for MRI systems**

Indications for Use

The GE Functional Brain Mapping Option is a software and hardware package that can be used to acquire, process and display the results of BOLD (blood oxygen level dependent) MRI scan studies taken in the presence of synchronized stimuli presented to a person being scanned. When interpreted by a trained physician these results may be useful in the determination of a course of treatment.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033867

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)