K073167

JAN - 4 2008

510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter:

Name:	GE Medical Systems, LLC 3200 N. Grandview Blvd., W-827 Waukesha, WI 53188
Contact:	Mark M. Stauffer Safety and Regulatory Engineer, MR modality Tel: 262-521-6891 Fax: 262-521-6439
Date Prepared:	September 27, 2007

Product Identification:

Proprietary Device Name:	BrainStat Software Option for GE Signa MR Scanners
Common Name:	Software Option for Magnetic Resonance Imaging System
Classification Name:	System, Nuclear Magnetic Resonance Imaging (21 CFR 892.1000, Product Code LNH)

Predicate Device(s):

Esaote S.p.A. Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera - K061429

Device Description:

The BrainStat Software Option is a software application to be used on GE Signa MR scanners. It is an evolutionary improvement to the post-processing application known as FuncTool on the HDx 1.5T and 3.0T MRI scanners (K052293).

Intended Use:

BrainStat is an automated post-processing software option that is designed to process a time-series of MR images acquired in the brain. BrainStat is indicated for use on dynamic magnetic resonance imaging data sets to depict parametric images that are calculated from the image intensity variations over time. These parametric images include the integrated-area of the signal intensity change, the time from the beginning of the change of intensity to the end of the intensity change, and the ratio of the integrated area to the time.

BrainStat provides information that when interpreted by a trained physician, can be useful in determining a diagnosis.

Comparison with Predicate:

The BrainStat Software Option is substantially equivalent to an analogous feature contained in a product currently marketed by Esaote S.p.A. as Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera - K061429.

Conclusion:

When used in conjunction with a GE Signa MR System, the BrainStat Software Option represents an evolutionary change to the image data post-processing capabilities called FuncTool, currently found on the GE HDx MRI system (K052293). This premarket notification submission demonstrates that the BrainStat software option is substantially equivalent to an analogous feature in Esaote's Dynamic MRI Software Option for C-scan, E-scan XQ and E-scan Opera because it has the same intended use and functionality.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 4 2008

GE Medical Systems, LLC
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K073167
Trade/Device Name: BrainStat Software Option for GE Signa MR Scanners
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 19, 2007
Received: December 20, 2007

Dear Mr. Borsai:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): _____

Device Name: BrainStat Software Option for GE Signa MR Scanner

Indications for Use:

BrainStat is an automated post-processing software option that is designed to process a time-series of MR images acquired in the brain. BrainStat is indicated for use on dynamic magnetic resonance imaging data sets to depict parametric images that are calculated from the image intensity variations over time. These parametric images include the integrated-area of the signal intensity change, the time from the beginning of the change of intensity to the end of the intensity change, and the ratio of the integrated area to the time.

BrainStat provides information that when interpreted by a trained physician, can be useful in determining a diagnosis.

Prescription Use __X__ **AND/OR** **Over-the-Counter Use** _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071367