NOV - 9 2005

GE Healthcare
P.O. Box 414, Milwaukee, WI 53201

K052978

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 Healthcare
PO Box 414
Milwaukee, WI 53201

Contact Person: Larry A. Kroger Ph.D.
Senior Regulatory Programs Manager

Telephone: 262- 544-3894

Fax: 262- 548-4768

Date Prepared: October 18, 2005

Device Name:

GE 1.5T Signa® HDe MR System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The 1.5T Signa® HDe MR System is substantially equivalent to the currently marketed GE 1.5T AND 3.0T Signa® HDx MR SYSTEM (K052293) with the main differences being a change to the receive chain architecture that includes fully digital eight independent receive channels.

Device Description:

The 1.5T Signa® HDe MR systems are a modification to the previously cleared MR systems K052293 which utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The 1.5T Signa® HDe Magnetic Resonance System features a superconducting magnet operating at 1.5T. The data acquisition system supports 1, 4, 8 independent receive channels and multiple independent coil elements per channel during a single acquisition series. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences. Images are acquired and reconstructed using 2D and 3D Fourier transformation techniques. The system is intended for high-resolution anatomical applications and short scan times. The 1.5T Signa® HDe MR system is also compatible in a mobile configuration.

Indications for Use:

The GE Signa® HDe MR system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The Signa® HDe MR system is indicated for use as a diagnostic imaging device to produce axial sagittal, coronal and oblique images, spectra, dynamic images of the internal structures and organs of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the Signa® HDe system reflect the spatial distribution of protons (hydrogen nuclei)

exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Comparison with Predicate Device:

The 1.5T Signa® HDe MR Systems are a modification of the previously cleared MR systems K052293 with the main differences being the change to the receive chain architecture that includes fully digital eight independent receive channels.

Summary of Studies:

The 1.5T Signa® HDe Magnetic Resonance Systems were evaluated to the appropriate NEMA performance standards as well as the IEC 60601-1 International Medical Equipment Safety standard and IEC 60061-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. The 1.5T Signa® HDe Magnetic Resonance System is comparable to the currently marketed GE 1.5T AND 3.0T Signa® HDx MR SYSTEM.

Conclusion:

It is the opinion of GE that the 1.5T Signa® HDe Magnetic Resonance System is substantially equivalent to the GE 1.5T AND 3.0T Signa® HDx Magnetic Resonance System. Usage of the 1.5T Signa® HDe Magnetic Resonance System 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

NOV - 9 2005

Mr. Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE HEALTHCARE
3200 Grandview Boulevard
WAUKESHA WI 53188

Re.: K052978
Trade/Device Name: GE. 1.5T Signa HDe MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 18, 2005
Received: October 24, 2005

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 (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 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 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" (21 CFR 807.97). 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) 443-6597 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

GE Healthcare
P.O. Box 414. Milwaukee, WI 53201

Indications for Use

510(k) Number (if known): K052978

Device Name:

GE 1.5T Signa® HDe MR System

Indications for Use:

The GE Signa® HDe MR system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The Signa® HDe MR system is indicated for use as a diagnostic imaging device to produce axial sagittal, coronal and oblique images, spectra, dynamic images of the internal structures and organs of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. The images produced by the Signa® HDe system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052978