K040444

GE Medical Systems

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

APR 1 4 2004

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
Milwaukee, WI 53201

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

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Date Prepared: February 19, 2004

Device Name:

GE Signa® 3.0T with Excite Magnetic Resonance System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

The GE Signa® 3.0T with Excite Magnetic Resonance System is substantially equivalent to the currently marketed Signa® 3.0T MR system (K022397) with the main differences being an addition of eight independent receive channels as part of a system upgrade.

Device Description:

The GE Signa® 3.0T with Excite Magnetic Resonance System is a modification to the Signa® 3.0T Magnetic Resonance System (K022397) which utilizes a superconducting magnet to acquire 2D single-slice and multi-slice, and 3D volume images. The GE Signa® 3.0T with Excite Magnetic Resonance System features a superconducting magnet operating at 3.0T. 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, short scan times, and multinuclear spectroscopy.

Indications for Use:

The GE Signa® 3.0T with Excite is a whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio and short scan times. The Signa® 3.0T with Excite MR System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images, spectroscopic images, and/or 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® 3.0T with Excite MR systems 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 Signa® 3.0T with Excite MR System is a modification of the Signa® 3.0T MR system (K022397) with the main differences being the addition of eight independent receive channels.

Summary of Studies:

The Signa® 3.0T with Excite MR System was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International Medical Equipment Safety standard and IEC 601-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. The Signa® 3.0T with Excite MR System is comparable to the currently marketed Signa® 3.0T Magnetic Resonance System.

Conclusion:

It is the opinion of GE that the Signa® 3.0T with Excite MR System is substantially equivalent to the Signa® 3.0T Magnetic Resonance System. Usage of the Signa® 3.0T with Excite MR 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

APR 1 4 2004

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
PO Box 414
MILWAUKEE WI 53201

Re: K040444
Trade/Device Name: GE Signa® 3.0T with EXCITE Magnetic Resonance System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Product Code: 90 LNH
Dated: January 19, 2004
Received: February 17, 2004

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): K040444

Device Name: **GE Signa® 3.0T with Excite MR System**

Indications for Use

The GE Signa® 3.0T with Excite is a whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio and short scan times. The Signa® 3.0T with Excite MR System is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images, spectroscopic images, and/or 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® 3.0T with Excite MR systems 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR

Over-The-Counter Use _____

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040444