K043262

JAN 12 2005

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: November 12, 2004

Device Name:

GE Signa® Excite MR Surgical Option

Marketed Device:

The GE Signa® Excite MR Surgical Option is substantially equivalent to the currently marketed Signa® 1.5T and 3.0T MR Excite System (K041476). The main difference is a modification to the table cradle that allows a separate transfer board to be transferred onto the MR Signa® table from a surgical table or patient transporter to enable traditional MR scanning of the patient.

Device Description:

The GE Signa® Excite MR Surgical Option is a MR table and transfer board that allows the patient to be moved from a surgical table to the MR scanner without changing the patient's position. It can be used in conjunction with a surgical table and other MR compatible equipment, such as but not limited to, patient monitoring equipment, IV pole, patient restraints, patient positioning accessories, and skull clamps that can be mounted to the patient transfer board, to facilitate ease of movement between the MR and surgical tables. The GE Signa® Excite MR Surgical Option can be used with single, or multiple operating rooms. The option will seamlessly integrate patient transfer from a surgical table and facilitate imaging within the GE Signa® Excite MR system. The patient, once transferred onto the MR system table, can then be scanned in the same manner as with traditional routine MR imaging. This device allows the GE Signa® Excite MR system to be utilized in a configuration of an integrated Surgical / MR suite.

Indications for Use:

The MR Surgical Option when integrated with the GE Signa® 3.0T or 1.5T magnetic resonance scanner (previously cleared K041476) can be used to produce head and whole body magnetic resonance images that are high resolution, high signal-to-noise ratio, with short scan times. The Signa® Excite MR system with Surgical Option is indicated for use as a diagnostic imaging device to produce axial 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® Excite system with Surgical Option 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. The GE Signa® Excite system with Surgical Option can provide MR images at various stages of a surgical procedure, and provides the capability to transfer a patient to the MR system table directly from a surgical table, or patient transport system. Images can be obtained using the MR scanner body coil, or local surface coils, and the surface coils used with the integrated system may / can accommodate sterile draping for surgical procedures.

Comparison with Predicate Device:

The GE Signa® Excite MR Surgical Option utilized the same MR scanner of the previously cleared Signa® 1.5T and 3.0T Excite MR System (K041476) with the main difference being a modification to the cradle that allows a separate transfer board to be transferred onto the MR Signa® table from a surgical table or patient transporter to enable traditional MR scanning of the patient.

Summary of Studies:

The GE Signa® Excite MR Surgical Option has been evaluated to the appropriate 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 GE Signa® Excite MR Surgical Option utilizes the currently marketed Signa® 1.5T and 3.0T Excite MR System (K041476). The modified table cradle in the Surgical Option adds the capability to allow a separate transfer board to be transferred onto the MR Signa® table from an operating table or patient transporter.

Conclusion:

It is the opinion of GE that the GE Signa® Excite MR Surgical Option is substantially equivalent to the Signa® Excite 1.5T and Signa® Excite 3.0T Magnetic Resonance System Tables. Usage of the GE Signa® Excite MR Surgical Option and any potential hazards of the modified table cradle have been addressed and do not present any safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Healthcare
W-400, P.O. Box 414
MILWAUKEE WI 53201

Re: K043262
Trade/Device Name: GE Signa® Excite MR Surgical Option
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: November 23, 2004
Received: November 24, 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 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.

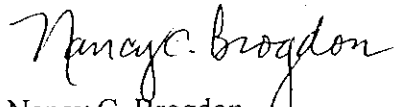
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

510(k) Number (if known): K043262

Device Name: GE Signa Excite MR Surgical Option

Indications For Use:

The MR Surgical Option when integrated with the GE Signa® 3.0T or 1.5T magnetic resonance scanner (previously cleared K041476) can be used to produce head and whole body magnetic resonance images that are high resolution, high signal-to-noise ratio, with short scan times. The Signa® Excite MR system with Surgical Option is indicated for use as a diagnostic imaging device to produce axial 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® Excite system with Surgical Option 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. The GE Signa® Excite system with Surgical Option can provide MR images at various stages of a surgical procedure, and provides the capability to transfer a patient to the MR system table directly from a surgical table, or patient transport system. Images can be obtained using the MR scanner body coil, or local surface coils, and the surface coils used with the integrated system may / can accommodate sterile draping for surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legrow

(Division Sign-Off)

Division of Reproductive, Abdominal,

K043262

Prescription Use ✓ OR Over-The-Counter Use_____ (Per 21 CFR 801.109)