



GE Healthcare

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

NOV 24 2004

510(k) Summary

12043112

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 8, 2004

Device Name:

Signa[®] Profile EXCITE MR System
Magnetic Resonance Diagnostic System, 21 CFR 892.1000, 90-LNH

Marketed Device:

Signa[®] Profile EXCITE MR System is substantially equivalent to the currently marketed the 0.2T Signa[®] Profile/i MR system (K033168) with the main differences of EXCITE technology with change of data acquisition hardware, host computer operated by new version software, and gradient power supply to AN8295Y, which enable maximum gradient slew rate changes to 34 T/m/s with maximum hardware capability of 46 T/m/s to allow for future customer upgrades. Maximum gradient amplitude is 19 mT/m.

Device Description:

Signa[®] Profile EXCITE MR System is a modification to the 0.2T Signa[®] Profile/i MR System (K033168) which utilizes a permanent magnet to acquire 2D single-slice and multi-slice, and 3D volume images. 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

Indications for Use:

The Signa[®] Profile EXCITE MR system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Signa[®] Profile EXCITE MR system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculoskeletal, vascular, cardiac, and neuro systems. The images produced by the Signa[®] EXCITE MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T₁), spin-spin relaxation



time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Signa® Profile EXCITE MR system may also be utilized for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

Comparison with Predicate Device:

The Signa® Profile EXCITE MR System is a modification of the Signa® Profile/i MR System (K033168) with the main differences of EXCITE technology with change of data acquisition hardware, host computer operated by new version software, and gradient power supply to AN8295Y, which enable maximum gradient slew rate changes to 34 T/m/s with maximum hardware capability of 46 T/m/s to allow for future customer upgrades. The Maximum gradient amplitude is 19 mT/m.

Summary of Studies:

The Signa® Profile EXCITE MR System 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 Signa® Profile EXCITE MR System is comparable to the currently marketed Signa® Profile/i MR System.

Conclusion:

It is the opinion of GE that the Signa® Profile EXCITE MR System is substantially equivalent to the Signa® Profile/i MR System. Usage of the Signa® Profile EXCITE MR System does not result in any new potential hazards.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 2004

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

Re: K043112
Trade/Device Name: GE 0.2T Signa[®] Profile
EXCITE MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: November 8, 2004
Received: November 10, 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 (Premarket Approval), 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.

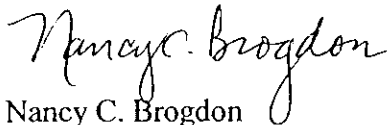
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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



STATEMENT OF INTENDED USE

510(k) Number (if known): K043112

Device Name: **GE 0.2T Signa® Profile EXCITE MR System**

Indications for Use

The Signa® Profile EXCITE MR system is an open, whole body scanner designed to support improved higher resolution imaging and shorter scan times. The Signa® Profile EXCITE MR system is indicated for use as a diagnostic imaging device to produce transverse, sagittal, coronal and oblique images of the internal structures and organs of the entire body, including, but not limited to, the musculoskeletal, vascular, cardiac, and neuro systems. The images produced by the Signa® Profile EXCITE MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Due to the 'open' design of the system, the Signa® Profile EXCITE MR system may also be utilized for imaging during interventional procedures when performed with MR compatible devices such as, in-room display and MR safe biopsy needles.

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043112

(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 _____