JUL 2 6 2004

K041921

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

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).

Applicant and Contact Information

Applicant & Initial Distributor: GE Healthcare Technologies
3200 N. Grandview Blvd.
Waukesha, WI 53188

Est. Registration No: 2183553- *[per 21 CFR 807.87(b)]*

Corresponding Official: Larry A. Kroger, Ph.D.

Title: Senior Regulatory Programs Manager

Mailing Address: GE Healthcare Technologies W-400
P.O. Box 414
Milwaukee, WI 53201

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E-mail: Larry.Kroger@med.ge.com

Device Name

0.2T 6-inch GP Coil
Magnetic Resonance Coil, 21 CFR 892.1000, 90-MOS

Marketed Device

The 0.2T 6-inch receive only GP coil is substantially equivalent to the currently marketed GE Signa Profile 9 inch coil (K972296), which is also a coil for 0.2T MR imaging.

Device Description

The GE 0.2T 6-inch GP Coil is designed for MR imaging of general purpose of the human anatomy. The coil is a 2-turn solenoid coil in series that provides high signal to noise ratio. The coil has blocking networks to decouple the coil during body coil transmit condition.

Indications for Use

The GE 0.2T 6-inch GP Coil is a 2-turn solenoid receive only coil designed for MR imaging. The coil has a soft pad, which helps to place the position to be examined in the center of the coil and provides comfort as well. The coil is a general-purpose coil that can be used to image the Cervical Spine, the neck, shoulder, and other extremity anatomy. The coil connects to the Signa MRI system by way of the interface connector.

Comparison with Predicate

The predicate device is the GE Signa Profile 9 inch coil (K972296). The coil is a similar design and technology. The main difference is the diameter of the coil.

Summary of Studies

The 0.2T 6-inch GP coil is evaluated to the appropriate NEMA performance standards as well as the IEC 60601-1 International Medical Equipment Safety standard and labeling requirement of IEC 60601-2-33 Particular Requirements for Safety of Magnetic Resonance Equipment for Medical Diagnosis. Testing was performed to demonstrate that the design met predetermined acceptance criteria.

Conclusion:

It is the opinion of GE that the 0.2T 6-inch GP Coil is substantially equivalent to the GE Signa Profile 9 inch coil (K972296). The GE 0.2T 6 inch GP Coil includes all the indications for use of that of the predicate device. The use of this device will 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

JUL 26 2004

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

Re: K041921
Trade/Device Name: GE 0.2T 6 inch GP coil
Regulatory Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: July 15, 2004
Received: July 16, 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 Healthcare Technologies
P.O. Box 414, Milwaukee, WI 53201

STATEMENT OF INTENDED USE

510(k) Number (if known): K041921

Device Name: 0.2T 6-inch GP Coil

Indications for Use:

The GE 0.2T 6-inch GP Coil is a 2-turn solenoid receive only coil designed for MR imaging. The coil has a soft pad, which helps to place the position to be examined in the center of the coil and provides comfort as well. The coil is a general-purpose coil that can be used to image the Cervical Spine, the neck, shoulder, and other extremity anatomy. The coil connects to the Signa Profile MRI system by way of the interface connector.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041921