K022669

SEP 6 2002

General Electric Company
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).

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: August 7, 2002

Device Name:

8 Channel Cardiac Phased Array Coil
Magnetic Resonance Coil, 21 CFR 892.1000, 90-MOS

Marketed Device:

The 8 Channel Cardiac Phased Array Coil is substantially equivalent to the currently marketed GE Cardiac Phased Array Coil (K971667) and the MRI Devices Corporation HRH-63-8 Head Array Coil (K013159).

Device Description:

The 8 Channel Cardiac Phased Array Coil is a modification to the Cardiac Phased Array Coil (K971667), which utilizes an increase in the number of independent receive channels from four to eight, integrates preamplifiers, and utilizes ASSET optimized geometry.

Indications for Use:

It is intended to be used in the heart and mediastinum regions for 2D and 3D Magnetic Resonance imaging.

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Comparison with Predicate Device:

The 8 Channel Cardiac Phased Array Coil is a modification of the GE Cardiac Phased Array Coil (K971667) with the main differences being an increase in number of independent receive channels from four to eight, the integration of preamplifiers, and the optimization for ASSET applications. The technological similarities to the MRI Devices Corporation HRH-63-8 Head Array Coil (K013159) include 8 independent receive channels, integrated preamplifiers, and ASSET optimized geometry.

Summary of Studies:

Testing was performed to demonstrate that the design modifications to the 8 Channel Cardiac Phased Array Coil meet predetermined acceptance criteria.

Conclusion:

It is the opinion of GE that the 8 Channel Cardiac Phased Array Coil is substantially equivalent to the GE Cardiac Phased Array Coil and the MRI Devices Corporation HRH-63-8 Head Array Coil. Usage of the 8 Channel Cardiac Phased Array Coil 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

SEP 6 2002

Larry Kroger, Ph.D.
Regulatory Programs Manager
GE Medical Systems
P.O. Box 414
MILWAUKEE WI 53201

Re: K022669
Trade/Device Name: 8 Channel Cardiac Phased Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: August 7, 2002
Received: August 12, 2002

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 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:

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" (21 CFR Part 807.97). 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

510(k) Number (if known): K022669

Device Name: 8 Channel Cardiac Phased Array Coil

Indications For Use:

It is intended to be used in the heart and mediastinum regions for 2D and 3D Magnetic Resonance imaging.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022669