GE Healthcare
510(k) Premarket Notification Submission

JUN 23 2010

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 6, 2010
Submitter:	GE Healthcare Coils (USA Instruments, Inc.) 1515 Danner Dr. Aurora, OH 44202
Primary Contact Person:	Mr. Michael S. Preto Regulatory Affairs Leader, MR GE Healthcare Coils (USA Instruments, Inc.) +1 330 995-8333 +1 330 562-1422
Secondary Contact Person:	Mr. Glen Sabin Regulatory Affairs Director, MR GE Healthcare (GE Medical Systems, LLC) Establishment Registration Number: 2183553 3200 N Grandview Blvd., Mail Code – W-827 Waukesha, WI 53188, USA Phone: 262-521-6848 Fax: 262-521-6439
Device: Trade Name:	8 Channel Cardiac Phased Array Coil
Common/Usual Name:	Coil, magnetic resonance, specialty
Classification Names:	21 CFR 892.1000, Magnetic resonance diagnostic device
Product Code:	90MOS
Predicate Device(s):	(1) K032045, 8 Channel Cardiac Phased Array Coil (2) K052584, 1.5T 12 Channel Body Array
Device Description:	The 8 Channel Cardiac Phased Array Coil is a surface coil used for Magnetic Resonance Imaging. It is tuned to image Proton nuclei in a receive-only configuration. It is comprised of 8 individual Phased Array coil elements each utilizing an integrated preamplifier to improve image quality. The geometry is optimized for use with parallel imaging techniques.
Intended Use:	The 8 Channel Cardiac Phased Array Coil is a receive-only RF Coil designed for use with 1.5T MRI systems manufactured by GE Healthcare. The indications for use include imaging of the heart, mediastinum, and pelvis regions for 2D and 3D Magnetic Resonance imaging. The nucleus excited is hydrogen.

Technology: The 8 Channel Cardiac Phased Array Coil has not been modified to accommodate the new anatomical region.

Determination of Substantial Equivalence: The 8 Channel Cardiac Phased Array Coil has comparable indications for use as its predicate devices:

Comparison with original 8 Channel Cardiac Phased Array Coil submission (K32045):

The 8 Channel Cardiac Phased Array Coil has not been modified to accommodate the new anatomical region.

Comparison with 1.5T 12 Channel Body Array Coil (K052584):

The 8 Channel Cardiac Phased Array Coil is an existing device which will now have indications for use that are similar to the existing 1.5T 12 Channel Body Array Coil.

Conclusion: GE Healthcare considers the 8 Channel Cardiac Phased Array Coil to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 23 2010

GE Healthcare Coils (USA Instruments, Inc.)
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K101492
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: MOS
Dated: May 28, 2010
Received: June 1, 2010

Dear Mr. Lehtonen:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: 8 Channel Cardiac Phased Array Coil

Indications for Use:

The 8 Channel Cardiac Phased Array Coil is a receive-only RF Coil designed for use with 1.5T MRI systems manufactured by GE Healthcare. The indications for use include imaging of the heart, mediastinum, and pelvis regions for 2D and 3D Magnetic Resonance imaging. The nucleus excited is hydrogen.

Prescription Use_X___ AND/OR Over-The-Counter Use_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Robert A Becker

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101492

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