510(k) Summary

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

Date: 16 February 2011

Submitter: GE Healthcare (GE Medical Systems, LLC)
Establishment Registration Number: 2183553
3200 N Grandview Blvd., Mail Code – W-827
Waukesha, WI 53188, USA

Primary Contact Person: Mr. Michael S. Preto
Regulatory Affairs Leader, MR
GE Healthcare Coils (USA Instruments, Inc.)
Phone: +1 330 995-8333
Fax: +1 330 562-1422
Email: michael.preto@ge.com

Secondary Contact Person: Mr. Glen Sabin
Regulatory Affairs Director, MR
GE Healthcare (GE Medical Systems, LLC)
3200 N Grandview Blvd., Mail Code – W-827
Waukesha, WI 53188, USA
Phone: 262-521-6848
Fax: 262-521-6439
Email: glen.sabin@ge.com

Device: Trade Name: GEM Option for 1.5T MRI systems

Common/Usual Name: Magnetic resonance diagnostic device

Classification Names: 21 CFR 892.1000
Product Code: 90LNH, 90MOS

Predicate Device(s): K091536, Optima MR450w

Device Description: The GEM Option for 1.5T MRI systems consists of a set integrated receive-only RF coils designed for use with 1.5T MRI systems manufactured by GE Healthcare. This coil set includes a head and neurovascular array, an anterior imaging array, a peripheral-vascular lower leg array, and a posterior imaging array integrated into the MR table for complete head-to-foot coverage. The coils can be used individually or combined to provide the anatomical coverage desired. The combined use of the entire GEM suite will facilitate high-resolution, high-SNR whole-body imaging from the top of the head down to the feet.

Intended Use: The GEM Option for 1.5T MRI systems is a set of receive-only RF surface coils designed for use with 1.5T MRI systems manufactured by GE Healthcare. The GEM Option for 1.5T MRI systems is indicated for use for: head, neck, brachial-plexus, spine, pelvis, hips, prostate, abdominal, cardiac, lower extremities, blood vessels, and long bone imaging. The nucleus detected is hydrogen.

Technology: Comparison with Optima MR450w (K091536):
The GEM Option for 1.5T MRI systems replaces the existing MR table with the GEM table. The system operates on the same principles with workflow improvement by reducing the need to change coils.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The GEM Option for 1.5T MRI systems has integrated surface coils to accommodate the improved workflow. The same non-clinical voluntary standards are used to demonstrate substantial equivalence of safety and performance:
IEC 60601-1: Electrical Safety – compliant with all applicable sections
IEC 60601-1-2: Electromagnetic Compatibility – compliant with all applicable sections (i.e. electrostatic discharge)
IEC 60601-2-33: Electrical Safety – compliant with all applicable sections
ISO 10993-1: Biocompatibility – determination of post market acceptability of materials

Clinical images are used to demonstrate substantial equivalence of performance.

Conclusion: GE Healthcare considers the GEM Option for 1.5T MRI systems to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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

GE Healthcare (GE Medical Systems, LLC)
Mr. Michael S. Preto
Regulatory Affairs Leader, MR
GE Healthcare Coils (USA Instruments, Inc.)
1515 Danner Drive
AURORA OH 44202

MAR - 7 2011

Re: K103335
Trade/Device Name: GEM Option for 1.5T MRI Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 16, 2011
Received: February 18, 2011

Dear Mr. Preto:

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,

Mary S Pastel

Mary Pastel, ScD.
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: GEM Option for 1.5T MRI systems

Indications for Use:

The GEM Option for 1.5T MRI systems is a set of receive-only RF surface coils designed for use with 1.5T MRI systems manufactured by GE Healthcare. The GEM Option for 1.5T MRI systems is indicated for use for: head, neck, brachial-plexus, spine, pelvis, hips, prostate, abdominal, cardiac, lower extremities, blood vessels, and long bone imaging. The nucleus detected 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)

Mary S Pastel

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

510(k) K123335

Page 1 of ___