GE Healthcare
510(k) Premarket Notification Submission

JAN 1 1 2013

510(k) Summary

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

Date: December 27, 2012

Submitter: GE Healthcare Coils, (USA Instruments, Inc)
Establishment Registration Number: 1529041
1515 Danner Dr.
Aurora, OH 44202-9273
USA

Primary Contact Person: Andrew Menden
Regulatory Affairs Manager
GE Healthcare (GE Medical Systems, LLC)
Establishment Registration Number: 2183553
3200 N Grandview Blvd., Mail Code – W-827
Waukesha, WI – 53188
USA
Phone: 262-521-6223
Fax: 414-908-9585

Secondary Contact Person: Glen Sabin
Regulatory Affairs Director
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: 262-364-2785

Device: Trade Name: 1.5T GEM RT Open Array
Common/Usual Name: Coil, Magnetic Resonance, Specialty
Classification Names: 21CFR 892.1000 – Magnetic resonance diagnostic device

Product Code: 90MOS
Predicate Device(s): K103335, GEM Option for 1.5T MRI Systems
Device Description: The 1.5T GEM RT Open Array is a receive only 8-Channel 8-element Posterior Phased Array, for use as an

option to the Optima MR450w MR Systems with GEM suites. It is a posterior array which can be inserted into the GEM Table cradle (K103335) at either the head or foot end.

Intended Use: The GEM RT Open Array Coil that is a part of the Oncology Suite is a receive-only RF coil designed for use with 1.5T MRI systems manufactured by GE Healthcare. The indications for use include the head, neck, and brachial plexus anatomies and vasculature imaging. The nucleus excited is hydrogen.

Technology: Comparison with GEM Option for 1.5T MRI Systems

The GE 1.5T GEM RT Open Array is a multi-element phased array RF Receive only coil with integrated preamplifiers. The 1.5T GEM RT Open Array coil operates on the same principles and is an addition to the GEM suite of coils (K103335). The GEM RT Open Array is designed to fit into the GEM table at the head or foot end adjacent to where the existing integrated posterior array in the GEM table resides.

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:

The GE 1.5T GEM RT Open Array has used the same non-clinical voluntary standards 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

NEMA MS-9: SNR and Uniformity of Phased Array Coils – compliant with all applicable sections

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 1.5T GEM RT Open Array, did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission.

Conclusion: GE Healthcare considers the 1.5T GEM RT Open Array 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 Center – WO66-G609
Silver Spring, MD 20993-002

January 11, 2013

GE Healthcare Coils (USA Instruments, Inc)
% Mr. Andrew Menden
1515 Danner Dr.
Aurora, OH 44202-9273

Re: K123327
Trade/Device Name: 1.5T GEM RT Open Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: October 25, 2012
Received: October 26, 2012

Dear Mr. Menden:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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* Diagnostics and Radiological Health 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,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K123327

Device Name: 1.5T GEM RT Open Array

Indications for Use:

The GEM RT Open Array Coil that is a part of the Oncology Suite is a receive-only RF coil designed for use with 1.5T MRI systems manufactured by GE Healthcare. The indications for use include the head, neck, and brachial plexus anatomies and vasculature imaging. The nucleus excited is hydrogen.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123327