GE Healthcare
510(k) Premarket Notification Submission

FEB 2 2 2013

510(k) Summary

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

Date: 26-Nov-2012

Submitter: GE Healthcare, (Wipro GE Healthcare Pvt Ltd)
122 (Part 1), John F. Welch Technology Centre,
Export Promotional Industrial Park, Whitefield,
Bangalore, INDIA 560066

Primary Contact Person: Shashidhar C S
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Device: Trade Name: 1.5T 4CH FLEX COIL

Common/Usual Name: Coil, magnetic resonance, specialty

Classification Names: 21CFR 892.1000, Magnetic resonance diagnostic device
Product Code: MOS

Predicate Device(s): K030953, GE 3.0T General Purpose Flex Coil

Device Description: The 1.5T 4CH Flex Coils are receive-only coils designed to provide images of various parts of human body. The flexible coil is wrapped around the anatomy of interest, such as an elbow or knee or can be used for planar imaging.
The 1.5T 4CH Flex coils are available in two models –

1.5T 4CH Large Flex coil and 1.5T 4CH Small Flex Coil, and are designed for use with GE 1.5T MR systems.

Intended Use: The Flex Coils are designed to produce diagnostic images of human anatomies and are used as general purpose coils. The Flex Coils are receive-only coils designed to be used with 1.5T MRI systems manufactured by GE Healthcare to provide images of various parts of human body including shoulder, elbow, wrist, knee, hip and ankle. Large flex coil can be used for scanning large anatomy and small flex coil can be used for scanning smaller anatomy. The flexible coil is wrapped around the anatomy of interest, such as an elbow or knee or can be used for planar imaging.

Technology: 1.5T 4CH Flex Coils are flexible and can be wrapped around the anatomy of interest, which is similar to its predicate device.

1.5T 4CH Flex coils are General Purpose receive only coils with 4 elements and integrated preamplifiers.

1.5T 4CH Flex coils are based on phased array technique for combining the images from 4 different channels. Coils are tuned to the proton frequency of 63.86MHz.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The 1.5T 4CH Flex Coil complies with voluntary standards IEC60601-1, IEC60601-2-33, IEC60601-1-2, ISO14971, and ISO10993-1.

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing
- Integration testing
- Safety testing

- Maximum B1 Peak test – This test is to verify the coil's ability to withstand maximum B1 peak fields and high B1 field energy concentrations without posing a risk to safety through arcing or voltage breakdown
- Blocking Network analysis - This test determines the effectiveness of the blocking networks(s) for transmit decoupling to ensure safety and to minimize B1 distortion
- Surface temperature test under normal condition
- Surface temperature test under unplugged condition

Summary of Clinical Tests:

Internal scans within GE Healthcare facility were performed to obtain sample clinical images. The subject of this premarket submission, 1.5T 4CH Flex Coil did not require external clinical studies to support substantial equivalence

Conclusion: GE Healthcare considers the 1.5T 4CH Flex Coil to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 22, 2013

Shashidhar C S
Regulatory Affairs Leader
WIPRO GE HEALTHCARE PRIVATE, LTD.
122 (Part 1) John F Welch Trading Centre, EPIP, Whitefield Rd
BANGALORE, INDIA 560066

Re: K123681
Trade/Device Name: 1.5T 4CH FLEX COIL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 26, 2012
Received: November 30, 2012

Dear Mr. Shashidhar C S:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K123681

Device Name: 1.5T.4CH FLEX COIL

Indications For Use:

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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)