GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

MAY 2 3 2013

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

Date: January 11, 2013

Submitter: GE Healthcare (GE Medical Systems, LLC)
3200 N. Grandview Blvd
Waukesha, WI 53188

Primary Contact Person: Michelle Huettner
Regulatory Affairs Leader, Magnetic Resonance
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Device Trade Name: Discovery MR750w 3.0T

Common/Usual Name: Magnetic Resonance Imaging System

Classification Names: Magnetic Resonance Diagnostic Device

Product Code: LNH

Predicate Device(s): Discovery MR750w 3.0T (K103327)

Device Description: The Discovery MR750w 3.0T features a superconducting magnet operating at 3.0 Tesla. The data acquisition system accommodates up to 32 independent receive channels in various increments, and multiple independent coil elements per channel during a single acquisition series. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of elements exhibiting magnetic resonance. The system can image in the sagittal, coronal, axial, oblique and double oblique planes, using various pulse sequences and reconstruction algorithms. The Discovery MR750w 3.0T uses multi-drive RF transmit for imaging of the head and body regions. The Discovery MR750w 3.0T is designed to conform to NEMA DICOM standards.

Intended Use:

The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

Technology:

The Discovery MR750w 3.0T employs the same fundamental scientific technology as its predicate device Discovery MR750w 3.0T (K103327). It is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It employs the same multi-drive RF transmit technology as its predicate. The modified device enables multi-drive RF transmit for head scanning, in addition to body scanning. There have been no hardware changes to enable multi-drive RF transmit for head scanning, it is solely a software change.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Discovery MR750w 3.0T and its applications comply with the following voluntary standards:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4

- IEC 60601-2-33

In addition, this MR scanner is in compliance with the applicable NEMA standards, including NEMA MS1, NEMA MS2, NEMA MS3, NEMA MS4, NEMA MS5, NEMA MS8, NEMA MS9, and NEMA PS3.1- 3.18.

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

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

In addition, numerical simulations were conducted to demonstrate the safety of the multi-drive RF transmit system.

The non-clinical tests have been summarized in the Verification testing that was completed for the modified Discovery MR750w 3.0T System. The testing was completed with passing results per the pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicate (Discovery MR750w 3.0T K103327) because it was also developed under quality assurance Design Controls. In addition, it is in compliance to the same Standards.

Summary of Clinical Tests:

The subject of this premarket submission, Discovery MR750w 3.0T, did not require clinical studies to support substantial equivalence. Internal scans were conducted as part of validation for workflow and image quality. The

clinical results demonstrated that the Discovery MR750w 3.0T maintains the same imaging performance results as its predicate device, the Discovery MR750w 3.0T (K103327). Sample clinical images are included in this submission.

Indications for Use:

The indications for use and intended use for the modified device are identical to the unmodified device.

Conclusion: GE Healthcare considers the Discovery MR750w 3.0T 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 20993-0002

GE Medical Systems, LLC (dba GE Healthcare)
% Ms. Michelle Huettner
Regulatory Affairs Leader, Magnetic Resonance
3200 N. Grandview Blvd.
WAUKESHA WI 53188

May 23, 2013

Re: K130115
Trade/Device Name: Discovery MR750w 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: April 22, 2013
Received: April 23, 2013

Dear Ms. Huettner:

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 contact 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. 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,

Michael D. O'Hara for

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): K130115

Device Name: Discovery MR750w 3.0T

Indications for Use:

The Discovery MR750w 3.0T is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. It is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images, parametric maps, and/or spectra, dynamic images of the structures and/or functions of the entire body, including, but not limited to, head, neck, TMJ, spine, breast, heart, abdomen, pelvis, joints, prostate, blood vessels, and musculoskeletal regions of the body. Depending on the region of interest being imaged, contrast agents may be used. The images produced by the Discovery MR750w 3.0T reflect the spatial distribution or molecular environment of nuclei exhibiting magnetic resonance. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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) K130115