



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

GE Medical Systems, LLC
% Mr. Jason Ma
Regulatory Affairs Leader
Magnetic Resonance Imaging Modality
3200 N. Grandview Blvd.
WAUKESHA WI 53188

June 9, 2016

Re: K160618

Trade/Device Name: Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH

Dated: May 11, 2016

Received: May 13, 2016

Dear Mr. Ma:

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 Industry and Consumer Education 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” (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 Industry and Consumer Education 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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive, slightly slanted style.

Robert Ochs, Ph.D.
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)

K160618

Device Name

Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and Optima MR450w 1.5T

Indications for Use (Describe)

The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems are whole body magnetic resonance scanners 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 MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Date:	January 18, 2016
Submitter:	GE Healthcare, (GE Medical Systems, LLC) 3200 N Grandview Blvd. Waukesha, WI 53188
Primary Contact Person:	Jason Ma Regulatory Affairs Leader, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-548-2899 Fax: 414-908-9585
Secondary Contact Person:	Steven Kachelmeyer Regulatory Affairs Director, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-548-2432 Fax: 414-908-9585
Device Trade Name:	Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and Optima MR450w 1.5T
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	892.1000
Product Code:	LNH
Predicate Device(s):	Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and Optima MR450w 1.5T [K142085]
Device Description:	The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T are whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio, and short scan times. The systems feature a superconducting magnet operating at 1.5 Tesla or 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

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	<p>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.</p> <p>This Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and the Optima MR450w 1.5T systems are designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).</p> <p>Modification for which this Special 510(k) is being filed is a Training PC which was introduced in the DV25.1 program. This modification allows users to train new technologist, optimize protocols, and evaluate pulse sequence development in the off-line environment.</p>
<p>Intended Use:</p>	<p>The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems are whole body magnetic resonance scanners 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.</p> <p>The images produced by the Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems 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.</p>

GE Healthcare
510(k) Premarket Notification Submission



Technology:	The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and Optima MR450w 1.5T employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	<p><u>Summary of Non-Clinical Tests:</u></p> <p>The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T systems with the addition of the new feature training PC complies with the NEMA standards, including NEMA PS3.1-3.20 for DICOM conformance.</p> <p><i>The following quality assurance measures were applied to the development of the system with the addition of the new feature training PC:</i></p> <ul style="list-style-type: none"> • <i>Risk Analysis</i> • <i>Requirements Reviews</i> • <i>Design Reviews</i> • <i>Testing on unit level (Module verification)</i> • <i>Integration testing (System verification)</i> • <i>Simulated use testing (Validation)</i> <p><u>Summary of Clinical Tests:</u></p> <p>The modification that prompted this submission did not require clinical testing.</p>
Conclusion:	GE Healthcare considers the Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, and Optima MR450w 1.5T to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).