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

March 17, 2017

GE Medical Systems, LLC
% Mary A Mayka, Ph.D.
Regulatory Affairs Manager
3200 Grandview Blvd.
WAUKESHA WI 53188

Re: K163331
Trade/Device Name: SIGNA Architect, SIGNA Artist, Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: February 17, 2017
Received: February 21, 2017

Dear Dr. Mayka:

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163331

Device Name
SIGNA Architect, SIGNA Artist, Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T and the Optima MR450w 1.5T

Indications for Use *(Describe)*

The SIGNA Architect, SIGNA Artist, 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 SIGNA Architect, SIGNA Artist, 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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GE Healthcare

510(k) Premarket Notification Submission

Section 05: 510(k) Summary

Discovery MR750w 3.0T, Discovery MR750 3.0T, Optima MR450w 1.5T, Discovery MR450 1.5T, SIGNA Architect, SIGNA Artist

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GE Healthcare
510(k) Premarket Notification Submission

In accordance with 21 CFR 807.92 the following summary of information is provided:	
Date:	November 22, 2016
Primary Contact Person:	Mary A. Mayka, Ph.D. Regulatory Affairs Manager GE Healthcare Phone: 262-527-3148 Fax: 262-364-2785
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848 Fax: 414-908-9585
Device Trade Name:	Discovery MR750w 3.0T, Discovery MR750 3.0T, Optima MR450w 1.5T, Discovery MR450 1.5T, SIGNA Architect, SIGNA Artist
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
Product Code:	LNH
Predicate Devices:	K160618: Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T, SIGNA Architect, SIGNA Artist
Device Description:	The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T, SIGNA Architect and SIGNA Artist systems are whole body magnetic resonance scanners designed to support high resolution, high signal-to-noise ratio, and short scan times. The systems each feature a superconducting magnet. The data acquisition system accommodates up to 128 independent receive channels in various increments and multiple independent coil elements per channel during a single acquisition series. Each 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. Each system can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences and reconstruction algorithms. The Discovery MR750 3.0T, Discovery MR450 1.5T, Discovery MR750w 3.0T, Optima MR450w 1.5T, SIGNA Architect, SIGNA Artist systems are designed to conform to

	NEMA DICOM standards (Digital Imaging and Communications in Medicine). The original description hasn't changed from predicate devices (K160618), other than reflecting the additional receive channels available. The modifications to these systems include the MAGiC DWI and CardioMaps software features, delivered via the DV26 program. The proposed software features will be ported over to other GE Healthcare MR systems based on appropriate design controls and evaluation of the change in accordance with FDA's Guidance—Deciding When to Submit a 510(k) for a Change to an Existing Device.
Indications for Use:	The SIGNA Architect, SIGNA Artist, 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 SIGNA Architect, SIGNA Artist, 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.
Comparison of Intended Use	The addition of the proposed software features does not impact the indications for use. The indications for use have not changed, other than the addition of the SIGNA Architect and SIGNA Artist systems (K160618/001 and K160618/002). Therefore, the intended use is the same as the predicate device in accordance with the FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", dated 28 July 2014.

Comparison of Technological Characteristics:	The MR systems with the proposed software features employ the same fundamental technology as the predicate devices.
Performance Data:	Summary of Non-Clinical Tests: The changes are software only features and comply with the following voluntary standards: • AAMI/ANSI 62304 • AAMI/ANSI ES60601-1 • IEC 60601-2-33 The following quality assurance measures were applied to the development of the device: • 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) The non-clinical tests have been summarized in this 510(k). Phantom testing for both Synthetic DWI and CardioMaps was completed to demonstrate acceptable performance. Testing was completed with passing results per the pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicates because it was also developed under quality assurance Design Controls. Summary of Clinical Tests: Sample clinical images are included in this submission in accordance with the MR guidance on premarket notification submissions.
Conclusion:	The GE MR systems with the modified software features have the same intended use as the predicate. This 510(k) submission includes information on the technological characteristics of the proposed software features, as well as performance data demonstrating that the features are as safe and effective as the predicate, and does not raise different questions of safety and effectiveness. In conclusion, GE Healthcare believes that the MR systems with the modified software features are substantially equivalent to the predicate devices.