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 (GE Healthcare)
% Mary A. Mayka, Ph.D.
Regulatory Affairs Manager
3200 N. Grandview Blvd.
WAUKESHA WI 53188

July 14, 2017

Re: K171128
Trade/Device Name: SIGNA™ Premier
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: April 14, 2017
Received: April 17, 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,

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)*
k171128

Device Name
SIGNA(TM) Premier

Indications for Use *(Describe)*
The SIGNA(TM) Premier system 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 SIGNA(TM) Premier system 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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k171128

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date:	April 14, 2017
Submitter:	GE Medical Systems, LLC (GE Healthcare) 3200 N. Grandview Blvd., Waukesha, WI 53188 USA
Primary Contact Person:	Mary A. Mayka, Ph.D. Regulatory Affairs Manager GE Healthcare Phone: 262-527-3148 Fax: 262-364-2785
Secondary Contact Person:	James McMahon Senior Director, Regulatory Affairs GE Healthcare Phone: 508-382-2858 Fax: 262-364-2785
Device Trade Name:	SIGNA™ Premier
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000
Product Code:	LNH, LNI, MOS
Predicate Device(s):	SIGNA™ Architect (K163331)

GE Healthcare
510(k) Premarket Notification Submission

Device Description:	SIGNA™ Premier is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times, and is designed for improved patient comfort and workflow. The system features a 3.0T superconducting magnet with a 70cm bore size and can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences, imaging techniques and reconstruction algorithms. The system is designed to conform to NEMA DICOM standards (Digital Imaging and Communications in Medicine).
Indications for Use	The SIGNA™ Premier system 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 SIGNA™ Premier system 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 SIGNA™ Premier employs the same fundamental scientific technology as its predicate devices. SIGNA™ Premier builds on the 3.0T wide bore magnet, TDI RF architecture and SIGNA™Works software platform and application suite. The following is a summary of the different technology characteristics from the predicate devices: • Newly designed gradient system • Expanded RF receive chain capabilities • Redesigned body coil • Updated patient table • Updated software version

Comparison of Indications for Use	The changes in technology do not impact the indications for use. The indications for use have not changed, other than to reflect the SIGNA™ Premier product name. 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	Overall, the SIGNA™ Premier employs the same fundamental scientific technology as the predicate device. **System Design:** There are two notable technological differences between the SIGNA™ Premier and the predicate device: a newly designed gradient system and an expanded channel count for the RF receive chain. The differences are summarized below: • Gradient system: The SIGNA Premier can deliver a maximum gradient amplitude of 80 mT/m and maximum gradient slew rate of 200 T/m/s compared to the predicate's maximum gradient amplitude of 44 mT/m and maximum gradient slew rate of 200 T/m/s. • RF receive chain**:** The SIGNA™ Premier is equipped with 146 receive channels as compared to the predicate's 128 channels. **Operating Principles:** The SIGNA™ Premier functions using the same operating principles as the predicate device. **Materials:** The SIGNA™ Premier and the predicate device both use flame retardant materials. **Safety and Performance Testing:** Both the SIGNA™ Premier and the predicate device comply with the same safety and performance testing (see Determination of Substantial Equivalence, below).

	These technological differences do not raise any different questions regarding safety and effectiveness. Both devices must address questions of whether they provide an adequate level of image quality appropriate for diagnostic use. The performance data described in this submission include results of both bench testing and clinical testing that show the image quality performance of SIGNA™ Premier compared to the predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The SIGNA™ Premier and the predicate device were subject to similar risk management testing to demonstrate substantial equivalence of safety and performance. Testing to the following voluntary standards included: • AAMI/ANSI ES60601-1 • IEC 60601-1-2 • IEC 60601-2-33 • AAMI/ANSI 62304 • ISO 10993-1 In addition, the SIGNA™ Premier complies with applicable NEMA MS standards for MRI and NEMA PS3 standard for DICOM, as does the predicate device. Both the SIGNA™ Premier and the predicate device have a successful biocompatibility track record, as demonstrated by ISO 10993 testing and by their history of use in previously cleared devices. The following quality assurance measures were applied to the development of the subject device, as they were for the predicate device: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Simulated use testing (Validation)

	Summary of Clinical Tests: The subject of this premarket submission, the SIGNA™ Premier, did not require clinical studies to support substantial equivalence. Sample clinical images have been included in this submission. The sample clinical images demonstrate acceptable diagnostic image performance of the SIGNA™ Premier in accordance with the FDA Guidance "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" issued on November 18, 2016. The image quality of the SIGNA™ Premier is substantially equivalent to that of the predicate device. Substantial Equivalence Conclusion: The indications for use of the proposed device are comparable to the claimed predicate device. The SIGNA™ Premier employs equivalent technology to the claimed predicate device. Additionally, the results from the above non-clinical tests demonstrate that the device performs as intended. Therefore, the SIGNA™ Premier is substantially equivalent to the predicate device to which it has been compared.
Conclusion:	In conclusion, GE Healthcare considers the SIGNA™ Premier to be as safe, as effective, with performance that is substantially equivalent to the predicate device.