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 29, 2016

GE Healthcare
% Mr. Glen Sabin
Regulatory Affairs Director
3200 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K160621
Trade/Device Name: SIGNA Pioneer
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 3, 2016
Received: March 4, 2016

Dear Mr. Sabin:

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)*
k160621

Device Name
SIGNA Pioneer

Indications for Use *(Describe)*

The SIGNA Pioneer 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 Pioneer 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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Section 5: 510(k) Summary

SIGNA Pioneer

510(k) Summary

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

Date:	March 25, 2016
Submitter:	GE Healthcare, (GE Healthcare Japan Corporation) 7-127, Asahigaoka 4-chome, Hino-shi, Tokyo 191-8503 JAPAN
Primary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848
Secondary Contact Person:	Steve Kachelmeyer Senior Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Phone: 262-548-2432
Device Trade Name:	SIGNA Pioneer
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names: Product Code:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000 LNH
Predicate Device:	SIGNA Pioneer (K143345)
Device Description:	The SIGNA Pioneer features a 3.0T superconducting magnet with a 70cm bore size The RF receiver is equipped with up to 97 RF channels. The system uses a combination of time-varying magnetic fields (gradients) and RF transmissions to obtain information regarding the density and position of nuclei 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 SIGNA Pioneer uses multi-drive RF transmit for imaging of the head and body regions. The SIGNA Pioneer is designed to conform to NEMA DICOM standards.

Intended Use:	The SIGNA Pioneer 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 Pioneer 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 Pioneer employs the same fundamental scientific technology as its predicate device. The SIGNA Pioneer system has been modified by the introduction of a new 65 receive channel configuration, in addition to the previously cleared 97 channel configuration. The modified SIGNA Pioneer system also includes enhancements to the software that controls Specific Absorption Rate (SAR).

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: Like the predicate device, the SIGNA Pioneer complies with the following voluntary standards: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-33 • ISO 10993-1 In addition, the SIGNA Pioneer complies with the applicable NEMA MS standards for MRI and NEMA PS3 standard for DICOM, as does the predicate device. The following quality assurance measures were applied to the development of the system, as they were for the predicate: • 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) Summary of Clinical Tests: The subject of this premarket submission, SIGNA Pioneer, did not require clinical studies to support substantial equivalence. Scanning of human subjects on the SIGNA Pioneer system has been conducted at GE Healthcare facilities as part of design validation activities in order to ensure that the modified device meets user requirements.
Conclusion:	The Indications for Use of the SIGNA Pioneer are identical to the predicate device. The modifications to the SIGNA Pioneer system do not change the fundamental scientific technology of the device. The results of design controls activities demonstrate that the SIGNA Pioneer is substantially equivalent to the predicate with regards to safety and efficacy. GE Healthcare considers the SIGNA Pioneer to be as safe, as effective, and performance is substantially equivalent to the predicate device.