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 Healthcare Japan Corporation
% Toru Shimizu
Regulatory Affairs Specialist
7-127, Asahigaoka 4-chome
Hino-shi, Tokyo 191-8503
JAPAN

August 20, 2015

Re: K143345
Trade/Device Name: SIGNA Pioneer
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: June 19, 2015
Received: June 22, 2015

Dear Toru Shimizu:

This letter corrects our substantially equivalent letter of July 10, 2015.

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,

Robert A Ochs

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

Enclosure

Section 4: Indications for Use Statement

SIGNA Pioneer

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)*

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:	August 7, 2015
Submitter:	GE Healthcare, (GE Healthcare Japan Corporation) 7-127, Asahigaoka 4-chome, Hino-shi, Tokyo 191-8503 JAPAN
Primary Contact Person:	Toru Shimizu Regulatory Affairs Specialist - Product GE Healthcare, (GE Healthcare Japan Corporation) Phone: +81-42-585-5344 Fax: +81-42-585-5911
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director - MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848
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, MOS
Predicate Device:	Discovery MR750w 3.0T (K142085)
Device Description:	The SIGNA Pioneer features a 3.0T superconducting magnet with a 70cm bore size. The RF receiver is equipped with 97 RF channels. The data acquisition system accommodates 32 channels for image reconstruction simultaneously. 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 following is a summary of the different technology characteristics from the predicate device: • Newly designed gradient system and RF receive chain including DDI and DST • Addition of new software features including Auto Navigator tracker placement, Auto Protocol Optimization and enhanced Image filter • TDI Coil Suite including DMS
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> 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 SIGNA Pioneer has been verified to meet the same safety criteria as the predicate device for local SAR for various anatomies. This verification was done by using local SAR human modeling simulations for RF multi drive transmit, as was done for 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 clinical images and clinical results summary demonstrate the acceptable diagnostic imaging performance of the SIGNA Pioneer including the additional new software features and TDI coil suite. The image quality of SIGNA Pioneer is substantially equivalent to that of the predicate device. Substantial Equivalence Conclusion: The Indications for Use of the SIGNA Pioneer are identical to the predicate device. The results from the above Non-Clinical and Clinical Tests demonstrate that the SIGNA Pioneer is substantially equivalent to the predicate with regards to safety and efficacy.
Conclusion:	GE Healthcare considers the SIGNA Pioneer to be as safe, as effective, and performance is substantially equivalent to the predicate device.