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

September 1, 2016

Ge Healthcare
Glen Sabin
Regulatory Affairs Director
3200 N. Grandview Blvd
Waukesha, Wisconsin 53188

Re: k161567
Trade/Device Name: Signa Voyager
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: June 3, 2016
Received: June 7, 2016

Dear Glen 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
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 Voyager

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)*
K161567

Device Name
SIGNA Voyager

Indications for Use *(Describe)*

The SIGNA Voyager is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan time imaging. The SIGNA Voyager is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images and/or spectra, dynamic images, and parametric maps of the internal structures and organs of the entire body. Body structures for evaluation include, but are 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 Voyager reflect the spatial distribution and/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 Voyager

Section 5: 510(k) Summary

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

Date:	June 03, 2016
Submitter:	GE Healthcare 3200 N. Grandview Blvd. Waukesha, WI 53188, USA
Primary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848
Secondary Contact Person:	Steve Kachelmeyer Regulatory Affairs Director - MR GE Healthcare, (GE Medical Systems, LLC) Phone: (262) 548-2432
Device Trade Name:	SIGNA Voyager
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names: Product Code:	Magnetic Resonance Diagnostic Device per 21 CFR 892.1000 LNH, MOS
Predicate Device:	SIGNA Pioneer (K160621) Optima MR450w 1.5T (DV25) (K142085)
Device Description:	The SIGNA Voyager system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The 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. The system can image in the sagittal, coronal, axial and oblique planes, using various pulse sequences and reconstruction algorithms. The system is offered as a new system installation, in either a fixed or a mobile configuration. The system features A 1.5T superconducting magnet with a 70cm bore size.

Intended Use:	The SIGNA Voyager is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan time imaging. The SIGNA Voyager is indicated for use as a diagnostic imaging device to produce axial, sagittal, coronal, and oblique images, spectroscopic images and/or spectra, dynamic images, and parametric maps of the internal structures and organs of the entire body. Body structures for evaluation include, but are 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 Voyager reflect the spatial distribution and/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.
Technological Characteristics:	The SIGNA Voyager employs the same fundamental scientific technology as its predicate devices. The following is a summary of the different technology characteristics from the predicate devices: • Updated RF Receive Chain • New version of software • Modified magnet and RF body coil • Updated TDI Coil Suite • New Computers

Performance Data:	Summary of Non-Clinical Tests: Like the predicate device, the SIGNA Voyager complies with the following voluntary standards: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-33 • ISO 10993-1 In addition, the SIGNA Voyager 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 predicates: • 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 sample clinical images demonstrate the acceptable diagnostic imaging performance of the SIGNA Voyager including the additional enhanced software features and all coils. The image quality of SIGNA Voyager is substantially equivalent to that of the predicate device.
Conclusion:	The SIGNA Voyager has the same intended use as the predicate devices. The differences in technological characteristics between the SIGNA Voyager and the predicate devices do not raise any different questions of safety or effectiveness. Performance data provided in this submission demonstrate that the SIGNA Voyager is as safe, as effective, and performs as well as or better than the predicate devices. GE Healthcare considers the SIGNA Voyager to be substantially equivalent to the SIGNA Pioneer and Optima MR450w devices.