GE Healthcare (Tianjin) Company Limited
℅ Yuan Ma
Regulatory Affairs Director
No. 266 Jinjsan Road, Tianjin Airport Economic Area
Tianjin 300308
CHINA

October 1, 2019

Re: K192426
Trade/Device Name: SIGNA Voyager/ SIGNA Voyager Quantum
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: September 6, 2019
Received: September 9, 2019

Dear Yuan Ma:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-

combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192426

Device Name
SIGNA Voyager / SIGNA Voyager Quantum

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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510(k) Summary

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

Date:	September 29, 2019
Submitter:	GE Healthcare (Tianjin) Company Limited No. 266 Jinjsan Road, Tianjin Airport Economic Area Tianjin, China
Primary Contact Person:	Yuan Ma Regulatory Affairs Director GE Healthcare (Tianjin) Company Limited Phone: +86 18101131106
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director GE Healthcare Phone: 262-521-6848
Device Trade Name:	SIGNA Voyager / SIGNA Voyager Quantum
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 Voyager (K161567)
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.

Technology:	The SIGNA Voyager employs the same fundamental scientific technology as its predicate device. The SIGNA Voyager system has been modified by the introduction of a new IPM magnet configuration, in addition to the previously cleared LCCw magnet configuration.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: Like the predicate device, the SIGNA Voyager complies with the following voluntary standards: • ANSI/AAMI ES60601-1 • IEC 60601-1-2 • IEC 60601-2-33 In addition, the SIGNA Voyager complies with the applicable NEMA MS standards for MRI 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 Voyager, did not require clinical studies to support substantial equivalence. Scanning of human subjects on the SIGNA Voyager 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 Voyager are identical to the predicate device. The modifications to the SIGNA Voyager system do not change the fundamental scientific technology of the device. The results of design controls activities demonstrate that the SIGNA Voyager is substantially equivalent to the predicate with regards to safety and efficacy. GE Healthcare considers the SIGNA Voyager to be as safe, as effective, and performance is substantially equivalent to the predicate device.