GE Healthcare (Tianjin) Company Limited
℅ Glen Sabin
Regulatory Affairs Director
GE Healthcare (GE Medical Systems, LLC)
3200 N Grandview Blvd.
WAUKESHA WI 53188

February 11, 2022

Re: K213603
Trade/Device Name: SIGNA™ Artist Evo
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: November 12, 2021
Received: November 15, 2021

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. 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); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213603

Device Name
SIGNA™ Artist Evo

Indications for Use *(Describe)*
The SIGNA™ Artist Evo 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™ Artist Evo 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date:	November 12, 2021
Submitter:	GE Healthcare (GE Healthcare (Tianjin) Company Limited) No. 266 Jingsan Road,Tianjin Airport Economic Area Tianjin, China 300308
Primary Contact Person:	Qiang Ding Regulatory Affairs Program Manager Phone: +86 13311385163 Email: Ding.Qiang@ge.com
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director Phone: 262-894-4968 Email: Glen.Sabin@ge.com
Device Trade Name:	SIGNA™ Artist Evo
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names:	Magnetic Resonance Diagnostic Device
Regulation Number:	21 CFR 892.1000
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS
Predicate Device:	SIGNA™ Artist (K202238)
Reference Device	SIGNA Architect (K202966)
Device Description:	The SIGNA™ Artist Evo system is a whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio, and short scan times. The system features a superconducting magnet. The data acquisition system accommodates up to 128 independent receive channels in various increments and multiple independent coil elements per channel during a single acquisition series. 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, oblique, and double

	oblique planes, using various pulse sequences and reconstruction algorithms.
Indications for Use:	The Indications for Use statement for the proposed device is identical to that of the predicate device: *The SIGNA™ Artist Evo 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™ Artist Evo 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 Characteristics:	Many of the technological characteristics of the proposed SIGNA™ Artist Evo system are unchanged from the predicate device. The SIGNA™ Artist Evo system reuses GE Healthcare 1.5T LCC magnets in the installed base, and introduces the new IRMW gradient coil. There are no changes to the RF transmit and receive subsystems compared to the predicate K202238. Key performance specifications (such as magnet stability and spatial homogeneity, maximum gradient strength, etc.) for the system are also unchanged. The SIGNA™ Artist Evo system also uses the same version software as the predicate device with some minor changes to accommodate the hardware differences. There are no changes to the pulse sequences, imaging protocols and image processing.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> The SIGNA™ Artist Evo and the predicate device were subject to similar risk management activities and performance testing to demonstrate substantial equivalence of safety and performance. Testing included compliance to the following voluntary standards: • AAMI/ANSI ES60601-1 • IEC 60601-1-2 • IEC 60601-2-33 • AAMI/ANSI 62304 • ISO 10993-1

	In addition, the SIGNA™ Artist Evo was tested in accordance with applicable NEMA MS standards for MRI, and complies with the NEMA PS3 standard for DICOM, as does the predicate device. Both the SIGNA™ Artist Evo and the predicate device are compliant with ISO 10993. 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) <u>Summary of Clinical Tests:</u> The subject of this premarket submission, the SIGNA™ Artist Evo, 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™ Artist Evo 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™ Artist Evo is substantially equivalent to that of the predicate device. <u>Substantial Equivalence Conclusion:</u> The indications for use of the proposed device are comparable to the claimed predicate device. The SIGNA™ Artist Evo 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™ Artist Evo is substantially equivalent to the predicate device to which it has been compared.
Conclusion Drawn from Performance Testing:	The proposed SIGNA™ Artist Evo system has been developed under GE Healthcare's quality system and is at least as safe and effective as the legally marketed predicate. The performance testing did not identify any new hazards, adverse effects, or safety or performance concerns that are significantly different from those associated with MR imaging in general. Therefore, GE Healthcare believes that SIGNA™ Artist Evo is substantially equivalent to the predicate device, and is safe and effective for its intended use.