GE Healthcare (Tianjin) Company Limited   September 4, 2020
℅ Mr. Glen Sabin
Regulatory Affairs Director
GE Healthcare (GE Medical System, LLC)
3200 N Grandview Blvd.
WAUKESHA WI 53188

Re: K202238
       Trade/Device Name: SIGNA Artist
       Regulation Number: 21 CFR 892.1000
       Regulation Name: Magnetic resonance diagnostic device
       Regulatory Class: Class II
       Product Code: LNH, LNI, MOS
       Dated: August 6, 2020
       Received: August 7, 2020

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. 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

Indications for Use

510(k) Number *(if known)*
K202238

Device Name
SIGNA Artist

Indications for Use *(Describe)*

The SIGNA Artist 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 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)*

[X] 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:	August 06, 2020
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 Leader 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
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 (K163331)
Device Description:	The SIGNA Artist 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. This 510(k) submission is for the SIGNA Artist 1.5T MR system, and has been triggered by the addition of the AIR Recon DL software feature.

	The AIR Recon DL feature has been previously cleared for use on the SIGNA Premier 3T system through K193282, which is used as a reference device for this submission.
Indications for Use:	The Indications for Use statement for the proposed device is identical to that of the predicate device:
	The SIGNA Artist 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 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.
	The addition of the AIR Recon DL feature does not impact the intended use of the SIGNA Artist system.
Technology Characteristics:	Many of the technological characteristics of the proposed SIGNA Artist system are unchanged from the predicate device. The SIGNA Artist system has been introduced an additional configuration with IPM magnet. There are no changes to gradient, and RF subsystems compared to the predicate K163331. Key performance specifications (such as magnet stability, maximum gradient strength and slew rate, etc.) for the system are also unchanged.
	The software used on the proposed SIGNA Artist system has been modified to include the AIR Recon DL feature. The User interface provides operators of the system with new options for selecting AIR Recon DL and adjusting the associated level of image noise reduction. The resulting images can have higher SNR and improved sharpness compared to images reconstructed without AIR Recon DL.
	AIR Recon DL has been previously cleared for use with GE Healthcare's 3T SIGNA Premier system through K193282. Due to the technical similarities, SIGNA Premier (K193282) is used as a reference device for this submission.

Determination of Substantial Equivalence:	**Summary of Non-Clinical Tests:** The AIR Recon DL feature has undergone the performance testing. These tests were designed to evaluate the AIR Recon DL feature and its impact on image quality, including SNR, sharpness, low contrast detectability, and noise spectral content. Analysis was performed to confirm that the feature does not introduce significant bias that might impact quantitative measurements based on signal intensity. The influence of motion during image acquisition on the performance of AIR Recon DL was also evaluated. The nonclinical testing demonstrated that AIR Recon DL does improve SNR and image sharpness while maintaining low contrast detectability and having minimal impacts to noise spectral content, average signal intensity, or the appearance of motion artifacts. AIR Recon DL was also able to maintain image SNR and did not sacrifice sharpness for images acquired with a reduced scan time. The nonclinical testing passed the defined acceptance criteria, and did not identify any adverse impacts to image quality or other concerns related to safety and performance. **Summary of Clinical Tests:** Objective measures of in vivo images were analyzed to confirm that AIR Recon DL improves SNR and image sharpness for typical clinical use cases. Additionally, sample images from clinically indicated scans were evaluated both with and without the AIR Recon DL feature. These samples included images using exogenous contrast and images involving pathology spanning a variety of anatomies and pulse sequences. Radiologists were asked to rate the images, and to comment on any notable aspects related to image quality. This study showed that the AIR Recon DL feature provides images with equivalent or better image quality, lesion conspicuity is maintained, and that the radiologists preferred the AIR Recon DL images for clinical use.
Conclusion Drawn from Performance Testing:	The nonclinical and clinical testing demonstrated that AIR Recon DL satisfies the product claims of improved SNR and image sharpness, and can enable shorter scan times while maintaining SNR and image sharpness. The proposed SIGNA Artist system with AIR Recon DL 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 and

| | performance concerns that are significantly different from those associated with MR imaging in general. |
| | Therefore, GE Healthcare believes that SIGNA Artist with AIR Recon DL is substantially equivalent to the predicate device, and is safe and effective for its intended use. |