GE Medical Systems, LLC
% Mr. Brian R. Zielski
Regulatory Affairs Leader
3200 Grandview Blvd.
WAUKESHA WI 53188

May 13, 2021

Re: K211118
Trade/Device Name: SIGNA 7.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: April 14, 2021
Received: April 15, 2021

Dear Mr. Zielski:

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)*

K211118

Device Name
SIGNA 7.0T

Indications for Use *(Describe)*

The SIGNA 7.0T 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 head and extremities.

The images produced by the SIGNA 7.0T system reflects 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 device is intended for patients > 20 kg / 44 lb.

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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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date:	April 13, 2021
Submitter:	GE Medical Systems, LLC (GE Healthcare) 3200 N. Grandview Blvd., Waukesha, WI 53188 USA
Primary Contact Person:	Brian R. Zielski Regulatory Affairs Leader Phone: 262-227-3596 Email: Brian.Zielski@GE.com
Secondary Contact Person:	Glen Sabin Senior Director, Regulatory Affairs Phone: 262-894-4968 Email: Glen.Sabin@GE.com
Device Trade Name:	SIGNA 7.0T
Common/Usual Name:	Magnetic Resonance Diagnostic Device
Classification Names: Regulation Number:	Magnetic Resonance Diagnostic Device 21 CFR 892.1000
Product Code: Primary: Secondary:	 LNH LNI, MOS
Predicate Device(s):	SIGNA 7.0T (K201615)

Device Description:	SIGNA 7.0T is a high performance magnetic resonance imaging system designed to support high resolution imaging at 7.0T in particular anatomical regions determined by the available RF coils. The system includes a 7.0T superconducting magnet and an ultra-high performance gradient coil with a 60 cm patient bore, supporting scanning in axial, coronal, sagittal, oblique, and double oblique planes using a variety of pulse sequences, imaging techniques, acceleration methods, and reconstruction algorithms. This 510(k) submission is for the SIGNA 7.0T MR System, and has been triggered by the addition of the AIR Recon DL software feature and inclusion of installed base magnet system upgrades.
Indications for Use	The addition of the AIR Recon DL feature and installed base magnet system upgrades does not impact the intended use of the SIGNA 7.0T system. The Indications for Use remain identical: *The SIGNA 7.0T 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 head and extremities.* *The images produced by the SIGNA 7.0T system reflects 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 device is intended for patients > 20 kg / 44 lb.*
Technology:	The SIGNA 7.0T employs the same fundamental scientific technology as its predicate device. The software used on the proposed SIGNA 7.0T 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. Upgrades to SIGNA 7.0T are also being expanded to be compatible with additional 7.0T magnets in the installed base.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The AIR Recon DL feature has undergone performance testing. These tests were designed to evaluate the AIR Recon DL feature and its impact on image quality, including SNR, sharpness, and low contrast detectability. The nonclinical testing demonstrated that AIR Recon DL does improve SNR and image sharpness while maintaining low contrast detectability. 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. Simulations and analyses were performed for the different installed base magnet types to ensure equivalence. 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. A reader study was performed on images with and without AIR Recon DL feature. Radiologists were asked to rate the images, and to comment on any notable aspects related to image quality. This study showed that AIR Recon DL feature provides images with better SNR and equivalent or better sharpness. The radiologists uniformly preferred the AIR Recon DL images for clinical evaluation.

Conclusion:	The Indications for Use of the SIGNA 7.0T are identical to the predicate device. The modifications to the SIGNA 7.0T system do not change the fundamental scientific technology of the device. The results of design controls activities demonstrate that the SIGNA 7.0T is substantially equivalent to the predicate with regards to safety and efficacy. GE Healthcare considers the SIGNA 7.0T to be as safe, as effective, and performance is substantially equivalent to the predicate device. In conclusion, GE Healthcare believes that SIGNA 7.0T with AIR Recon DL and installed base magnet system upgrades is substantially equivalent to the predicate device, and is safe and effective for its intended use.