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

October 15, 2020

Re: K201615
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
Dated: August 28, 2020
Received: August 31, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201615

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 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 device is intended for patients > 20 kg / 44 lbs.

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:	June 10, 2020
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: 262-521-6609 Email: Brian.Zielski@GE.com
Secondary Contact Person:	James McMahon Senior Director, Regulatory Affairs Phone: 508-382-2858 Email: James.D.McMahon@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 Premier (K193282)
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.
Indications for Use	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.
Comparison of Indications for Use	The changes in technology do not impact the indications for use. The indications for use have not changed, other than to reflect the SIGNA 7.0T product name and simplified anatomy of head and extremities, and patient weight limit.

	Therefore, the intended use is the same as the predicate device in accordance with FDA's guidance document "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*", dated 28 July 2014.
Technology:	The SIGNA 7.0T employs the same fundamental scientific technology as the predicate device. System Design: The most notable technological difference between the SIGNA 7.0T and the predicate device is the 7.0T B0 magnetic field compared to 3.0T. The SIGNA 7.0T design enables the capabilities that this higher B0 magnetic field contributes to MR imaging through the following key differences: • **RF Transmit chain**: The SIGNA 7.0T employs multiple and independent channels for RF transmission, and dedicated receiver array coils and detectors for high sensitivity signal reception. • **Gradient system**: The SIGNA 7.0T can deliver a maximum gradient amplitude of 113 mT/m and maximum gradient slew rate of 260 T/m/s compared to the predicate's maximum gradient amplitude of 80 mT/m and maximum gradient slew rate of 200 T/m/s. • **Applications**: The SIGNA 7.0T uses the SIGNA Works suite of applications, optimized for the advanced hardware and for the higher field strength to generate high resolution functional, structural, anatomical, vascular, and spectroscopic images. Operating Principles: The SIGNA 7.0T functions using the same operating principles as the predicate device. Materials: The SIGNA 7.0T and the predicate device both use flame retardant materials. Safety and Performance Testing: Both the SIGNA 7.0T and the predicate device comply with the same safety and performance testing (see Determination of Substantial Equivalence, below).

	These technological differences do not raise any different questions regarding safety and effectiveness. Both devices must address questions of whether they provide an adequate level of image quality appropriate for diagnostic use. The performance data described in this submission include results of both bench testing and clinical testing that show the image quality performance of SIGNA 7.0T compared to the predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The SIGNA 7.0T and the predicate device were subject to similar risk management testing to demonstrate substantial equivalence of safety and performance. Testing to the following voluntary standards includes: • ANSI/AAMI ES60601-1 • AAMI/ANSI/IEC 60601-1-2 • IEC 60601-2-33 • AAMI/ANSI/IEC 62304 • AAMI/ANSI/ISO 10993-1 In addition, the SIGNA 7.0T complies with applicable NEMA MS standards for MRI and NEMA PS3 standards for DICOM, as does the predicate device. 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)

	Summary of Clinical Tests: To evaluate the image quality performance of the SIGNA 7.0T system, assessments were performed by GE MR internal Clinical Applications Specialists and external Radiologist as part of a Reader Evaluation Study. The reader study was performed on images acquired on the proposed 7.0T system and predicate 3.0T system. Image series ranged from brain MR scans performed on normal subjects and subjects with self-reported common neuropathology, as well as knee images over a broad age range representative of a range of knee health. The study involved 4 U.S. board-certified radiologists evaluating proposed device's image diagnostic quality and usability, personal preferences, and general commentary using radiology terms against same subject images scanned on the predicate device. To set the PNS limits for the SIGNA 7.0T system, a direct determination study was conducted with adult human volunteers without reported pathology.
Conclusion:	The proposed SIGNA 7.0T was developed under GE Healthcare's quality system and is at least as safe and effective as the legally marketed predicate device. 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. In conclusion, GE Healthcare believes that SIGNA 7.0T is substantially equivalent to the predicate device, and is safe and effective for its intended use.