GE Healthcare (GE Medical Systems, LLC)
% Mr. Glen Sabin
Regulatory Affairs Director, MR
3200 N Grandview Blvd.
WAUKESHA WI 53188

April 10, 2020

Re: K193282
Trade/Device Name: SIGNA Premier
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: March 11, 2020
Received: March 12, 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

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)*

K193282

Device Name

SIGNA Premier

Indications for Use *(Describe)*

The SIGNA Premier 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 Premier 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: 26 November 2019

Submitter:
GE Medical Systems, LLC
3200 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact:
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Device Trade Name: SIGNA Premier

Common / Usual Name: MR System

Classification Name: Magnetic Resonance Diagnostic Device
Regulation Number: 21 CFR 892.1000
Primary Product Code: LNH
Secondary Product Codes: LNI, MOS

Predicate Device:
510(k) Number: K183231
Device Name: SIGNA Premier
Manufacturer: GE Medical Systems, LLC

Device Description:

SIGNA Premier is a whole-body magnetic resonance scanner featuring a 3.0T superconducting magnet with a 70cm bore size. Major elements of the system include the magnet, gradient coils, body RF transmit coil, RF receive subsystem, patient support system (table), host computer, and system software. The system is compatible with a suite of RF receive coils, and is capable of using various pulse sequences, imaging techniques and reconstruction algorithms.

This submission is prompted by the introduction of a new software feature called AIR Recon DL onto the SIGNA Premier system. AIR Recon DL is a deep-learning based reconstruction technique designed to improve signal-to-noise ratio (SNR) and image sharpness. The feature also enables shorter scan times while preserving SNR and image sharpness.

The addition of the AIR Recon DL feature involved modifications to the SIGNA Premier system software. There were no changes related to AIR Recon DL to the system's hardware components.

Indications for Use:

The Indications for Use statement for the proposed device is identical to that of the predicate device:

> *The SIGNA Premier 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 Premier 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 Premier system.

Comparison of Technological Characteristics:

Many of the technological characteristics of the proposed SIGNA Premier system are unchanged from the predicate device. There are no changes to the magnet, gradient, and RF subsystems compared to the predicate K183231. Key performance specifications (such as magnet homogeneity and stability, maximum gradient strength and slew rate, etc.) for the system are also unchanged.

The software used on the proposed SIGNA Premier 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.

Summary of Nonclinical Testing:

The AIR Recon DL feature has undergone testing with a digital reference object and phantom imaging. 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 Testing:

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 evaluation study was performed on AIR Recon DL images acquired across a variety of pulse sequences and anatomies. Radiologists were asked to perform blinded reads of both AIR Recon DL images and images without AL Recon DL. Comparisons were also made between AIR Recon DL images from shorter scan time acquisitions and images without AIR Recon DL taken with longer scan times. The results confirmed that the AIR Recon DL feature provides images with equivalent or better image quality in terms of the legibility of clinically relevant structures. The radiologists reading the images also indicated a preference for the AIR Recon DL images.

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 lesion conspicuity is maintained with AIR Recon DL, and that the radiologists preferred the AIR Recon DL images for clinical use.

Conclusions 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 Premier 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 or performance concerns that are significantly different from those associated with MR imaging in general.

Therefore, GE Healthcare believes that SIGNA Premier with AIR Recon DL is substantially equivalent to the predicate device, and is safe and effective for its intended use.