November 13, 2020

GE Healthcare (GE Medical Systems, LLC)
% Mr. Joseph Beach
Regulatory Affairs Leader, MR
3200 N Grandview Blvd.
WAUKESHA WI 53188

Re: K202966
Trade/Device Name: SIGNA Architect
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: September 28, 2020
Received: September 30, 2020

Dear Mr. Beach:

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,

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202966

Device Name
SIGNA Architect

Indications for Use *(Describe)*

The SIGNA Architect 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 Architect 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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Section 005

510(k) Summary

510(k) Summary

K202966

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

Date: September 29, 2020

Submitter:
GE Medical Systems, LLC
3200 N. Grandview Blvd.
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Primary Contacts:
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Device Trade Name: SIGNA Architect

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: K163331
Device Name: SIGNA Architect
Manufacturer: GE Medical Systems, LLC

Reference Devices:
510(k) Number: K162722
Device Name: HyperSense
Manufacturer: GE Medical Systems, LLC

510(k) Number: K142085
Device Name: DISCO
Manufacturer: GE Medical Systems, LLC

Device Description:

SIGNA Architect 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. Each 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. Each system can image in the sagittal, coronal, axial, oblique, and double oblique planes, using various pulse sequences and reconstruction algorithms.

This submission is prompted by the introduction of two new software features called **HyperSense 2.0** and **Star** onto **SIGNA Architect**. HyperSense 2.0 is an acceleration technique based on sparse data compressibility allowing scan time reduction while maintaining SNR efficiency. Star is a motion-robust, free-breathing imaging technique. **HyperSense 2.0** is a modification to the previously cleared HyperSense, while **Star** is a technique that can be used with the previously cleared DISCO feature. Both **HyperSense** and DISCO are listed above as reference devices along with their associated 510(k) submission numbers.

The addition of both the HyperSense 2.0 and Star features involved modifications to the SIGNA Architect system software. There were no changes from either of these features that were related 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 Architect 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 Architect 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 HyperSense 2.0 and Star does not impact the intended use of the SIGNA Architect system.

Comparison of Technological Characteristics:

Many of the technological characteristics of the proposed SIGNA Architect system are unchanged from the predicate device. There are no changes to the magnet, gradient, and RF subsystems compared to the predicate K163331. 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 Architect system has been modified to include the HyperSense 2.0 and Star features. The user interface provides operators of the system with new options for selecting these features and adjusting any parameters associated with them. However, the proposed SIGNA Architect system with HyperSense 2.0 and Star employs the same fundamental technology as the predicate device.

Summary of Nonclinical Testing:

The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on a Unit Level (Module Verification)
- Integration Testing (System Verification)
- Performance Testing (Verification)
- Safety Testing (Verification)
- Simulated Use Testing (Validation)

Exploratory testing was also performed to ensure that the proposed SIGNA Architect is at least as safe and effective as the predicate device. Verification documents, validation documents, and test reports have been provided for more details. No new questions of safety and effectiveness were raised during nonclinical testing.

Summary of Clinical Testing:

Studies were performed for both proposed HyperSense 2.0 and Star features.

An external reader evaluation study was performed for HyperSense 2.0. The images involved were generated using 3 different reconstruction techniques across different anatomies. Radiologists were asked to evaluate side-by-side image quality of the HyperSense 2.0 images compared to the predicate. Overall image quality and uniformity was acceptable.

External clinical testing was performed for the Star feature. Images produced by Star were judged to be of sufficient quality for diagnostic use by a U.S. Board Certified radiologist. Images from the assessment are provided.

Clinical testing confirms that both HyperSense 2.0 and Star can be used safely and effectively in a clinical setting.

Conclusions Drawn from Performance Testing:

Nonclinical and clinical testing demonstrates that the proposed SIGNA Architect with HyperSense 2.0 and Star is at least as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

The proposed SIGNA Architect system was developed under GE Healthcare's quality system. 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 the proposed SIGNA Architect with HyperSense 2.0 and Star is substantially equivalent to the predicate device, and is safe and effective for its intended use.