Siemens Medical Solutions USA, Inc.
Milind Dhamankar, M.D.
Sr. Clinical Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

July 12, 2019

Re: K191050
Trade/Device Name: MAGNETOM Aera and MAGNETOM Skyra with Software *syngo* MR E11E with Ischemic Heart Disease (IHD) Workflow
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, and MOS
Dated: April 17, 2019
Received: April 19, 2019

Dear Dr. Dhamankar:

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)*
K191050

Device Name
MAGNETOM Aera and MAGNETOM Skyra with Software syngo MR E11E with Ischemic Heart Disease (IHD) Workflow

Indications for Use *(Describe)*
Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.

Software syngo MR E11E with Ischemic Heart Disease (IHD) Workflow, when used with a gadolinium-based contrast agent (GBCA) approved for cardiac MRI (CMRI) is indicated for the acquisition and display of images of myocardial perfusion (stress, rest) and late gadolinium enhancement (LGE) during post-contrast CMRI examination in patients with known or suspected coronary artery disease (CAD).

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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K191050

510(k) Summary: MAGNETOM Aera and MAGNETOM Skyra

Company:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: April 17th, 2019

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR § 807.92.

1. General Information

Importer/Distributor:

Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Mail Code 65-1A
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

Manufacturing Sites:

Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen, Germany
Establishment Registration Number: 3002808157

SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
Siemens MRI Center
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Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Establishment Registration Number: 3004754211

2. Contact Person:

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3. Device Name and Classification:

Device Name	MAGNETOM Aera and MAGNETOM Skyra with Software *syngo* MR E11E with Ischemic Heart Disease (IHD) Workflow
Trade Name	MAGNETOM Aera, MAGNETOM Skyra
Classification Name	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS

4. Legally Marketed Predicate Device:

Device Name	MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Verio and MAGNETOM Avanto with Software *syngo* MR D13A
Trade Names:	MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Verio and MAGNETOM Avanto
510(k) Number:	K121434, cleared November 05, 2012
Classification Name	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS

5. Intended Use

The indications for use for the subject devices are the same as the predicate devices; only a section has been added to address the IHD Workflow feature (modification for this submission):

Your MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and

that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

Your MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.

Software *syngo* MR E11E with Ischemic Heart Disease (IHD) Workflow, when used with a gadolinium-based contrast agent (GBCA) approved for cardiac MRI (CMRI) is indicated for the acquisition and display of images of myocardial perfusion (stress, rest) and late gadolinium enhancement (LGE) during post-contrast CMRI examination in patients with known or suspected coronary artery disease (CAD).

6. Device Description:

MAGNETOM Aera and MAGNETOM Skyra with Software *syngo* MR E11E with IHD Workflow are the subject devices. The Software *syngo* MR E11E with IHD Workflow, when used with a gadolinium-based contrast agent (GBCA) approved for CMRI, extends the capability of the cleared Cardiac Dot Engine (K121434) for post-contrast CMRI exams for patients with known or suspected coronary artery disease (CAD).
Software *syngo* MR E11E with IHD Workflow is available for MAGNETOM Aera and MAGNETOM Skyra excluding the 24-channel configuration.

A. The cleared Cardiac Dot Engine (*syngo* MR D13A, K121434) helps acquisition and display of cardiac morphology and function (noncontrast CMRI).

   A comprehensive post-contrast CMRI exam includes stress/rest perfusion and late gadolinium enhanced (LGE) imaging. To accomplish post-contrast CMRI imaging, basic morphologic / functional imaging (noncontrast CMRI) is required. Therefore, the cleared Cardiac Dot Engine (*syngo* MR D13A, K121434) is a pre-requisite to the subject devices.

B. The Cardiac Dot Engine together with the IHD Workflow and a GBCA approved for post-contrast CMRI provides for a complete (pre- and post-contrast) examination.

Device Modifications:

The list below describes new software features. The primary predicate devices are modified to include a new Dot Workflow named "Ischemic Heart Disease" (IHD) Workflow for a post-contrast CMRI exam using pulse sequences already cleared in the USA (*syngo* MR D13A,

K121434). A new Dot Workflow “Ischemic Heart Disease” is added in Cardiac Dot Engine dropdown list, under the region “heart”. This Dot Workflow includes the following: six new post-contrast CMRI measurement protocols and one workflow step:

New Measurement protocols:

1. DynamicTest (test protocol for perfusion imaging without contrast agent)
2. DynamicStress (protocol for perfusion imaging under stress conditions)
3. DynamicRest (protocol for perfusion imaging under rest conditions)
4. DE_overview
   (protocol for delayed enhancement (DE) or LGE with low spatial resolution as an overview)
5. DE_seg_high-res_LAX
   (protocol for DE or LGE with high spatial resolution in long axis view)
6. DE_seg_high-res_SAX
   (protocol for DE or LGE with high spatial resolution in short axis view)

New workflow step:

1. Inject contrast agent. This step prompts the user to start the contrast agent injection for post-contrast CMRI exams.

7. Technological Characteristics

The subject devices, MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11E Software with IHD Workflow, have the same fundamental technological characteristics as the primary predicate devices, MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Verio and MAGNETOM Avanto with *syngo* MR D13A (K121434 cleared November 05, 2012) as well as the secondary predicate devices (K153343) with regard to the operational environment, programming language, operating system, and performance.

The software was modified to implement a new Dot IHD Workflow. Cardiac Dot Engine with IHD Workflow with software *syngo* MR E11E is composed of the Cardiac Dot Engine cleared in the US (K121434) and an additional Dot IHD Workflow to support post-contrast CMRI exam.

The MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11E Software with IHD Workflow conforms to the standard for software medical devices (IEC 62304:2015) and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics between the subject devices and predicate devices, including new software features, these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate devices.

8. Nonclinical Tests

The following performance testing was conducted on the subject devices:

1. Image quality assessments of the modified measurement protocols
2. Software verification and validation testing was completed in accordance with the FDA guidance document, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (May 11, 2005)

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

9. Clinical Tests

Extensive clinical testing was performed to ensure the safety and efficacy of the subject devices.

Verification and validation of the subject devices with IHD Workflow in Software *syngo* MR E11E without contrast agent usage were completed; all tests passed. In addition, the validation with contrast agent usage for device performance and indications for use is supported by clinical images from the GadaCAD studies. Refer to Section 14.4 "Clinical Studies - Cardiac MRI" of the GADAVIST™ (gadobutrol) injection U.S. package insert for additional description of GadaCAD results.

Two prospectively controlled, multi-national, single-arm clinical studies (GadaCAD1 and GadaCAD2) were performed by Bayer HealthCare AG to evaluate efficacy of post-gadobutrol cardiac MRI (CMRI) for the detection of coronary artery disease (CAD) in adult subjects with known or suspected CAD.

A total of 764 subjects with suspected or known CAD were evaluated in the GadaCAD studies: 376 subjects in GadaCAD1 and 388 subjects in GadaCAD2.

A standard total dose of 0.1 mmol/kg BW of gadobutrol administered in 2 bolus injections (0.05 mmol/kg at peak stress, followed ~10 minutes later by 0.05 mmol/kg at rest) was used in both GadaCAD1 and GadaCAD2. No additional gadobutrol was administered for LGE imaging.

Investigational sites performed CMRI in 1.5T and 3T MAGNETOM scanners that were running the Cardiac Dot Engine Pro software on *syngo* MR VD13A (Siemens Healthineers).

Cardiac Dot Engine Pro software used in the GadaCAD studies had two components: a Cardiac Dot Engine component for non-contrast CMRI that is cleared in the United States (*syngo* MR VD13A, K121434) and an investigational component for post-contrast CMRI specific measurement protocols and workflow that was released by Siemens Healthineers as a Works in Progress (WIP) component (*syngo* MR VD13A) to support post-gadobutrol CMRI examinations (stress and rest perfusion and LGE). The

Works in Progress (WIP) component (*syngo* MR VD13A) of Cardiac Dot Engine Pro used to support post-gadobutrol CMRI examinations in the GadaCAD clinical studies is identical to the IHD Workflow of the subject devices, except for the addition of a real-time wall-motion CMRI measurement after pharmacologic stress agent administration and prior to contrast injection in the GadaCAD studies. In addition, in the GadaCAD studies, inversion time (TI) for LGE acquisition was fixed at a pre-specified value, and flexibility for per-patient adjustment in the subject devices and for the use of other GBCAs approved for CMRI was not employed.

In the GadaCAD studies, the devices generated CMRI images (stress and rest perfusion and LGE) that were interpreted by qualified independent readers (radiologists and cardiologists experienced in CMRI). The post-gadobutrol CMRI specific acquisition protocols supported adequate detection of CAD in two multi-center, multinational clinical studies.

Efficacy results of GadaCAD studies support the device performance and the indication of "acquisition and display of images of myocardial perfusion (stress, rest) and late gadolinium enhancement (LGE) during post-contrast cardiac MR (CMRI) examination".

Select GadaCAD case studies are provided to illustrate acquired perfusion and LGE imaging.

10. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk management is ensured via ISO 14971:2007 compliance to identify and provide mitigation to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in hardware and software development, testing, and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards, such as the IEC 60601-1 series, to minimize electrical and mechanical risk. Software development is carried out according to the IEC 62304 standard for medical device software. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

The MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11E Software with IHD Workflow conforms to the applicable FDA recognized and international IEC, ISO and NEMA.

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ES60601-1:2005/(R)2012 and A1:2012	AAMI ANSI
19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2 Edition 4.0 2014-02	IEC
12-295	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic	60601-2-33 Ed. 3.2 B:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-89	General	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	60601-1-6 Edition 3.1 2013-10	IEC
5-114	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	IEC
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA

11. Substantial Equivalence and Conclusion

The subject devices, MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11E Software with IHD Workflow, have the same intended use as the primary predicate devices, MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Verio and MAGNETOM Avanto with *syngo* MR D13A (K121434).

The software was modified to implement a new Dot workflow called IHD Workflow. Cardiac Dot Engine with IHD Workflow with software *syngo* MR E11E is composed of the Cardiac Dot Engine cleared in the USA (K121434) and an additional Dot IHD Workflow to support post-contrast CMRI examination.

While there is a difference in technological characteristics between the subject devices and predicate devices (the new software workflow), this difference

has been tested and the conclusions from the non-clinical tests have shown that there were no additional questions of safety and effectiveness raised.

Siemens believes that the subject devices, MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11E Software with IHD Workflow are substantially equivalent to the predicate devices, MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Verio and MAGNETOM Avanto with *syngo* MR D13A and *syngo* MR E11E for MAGNETOM Aera and MAGNETOM Skyra.

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