Siemens Medical Solutions USA, Inc.
% Cordell Fields, Esq.
Regulatory Affairs Technical Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

February 13, 2018

Re: K173592
Trade/Device Name: MAGNETOM Aera, MAGNETOM Skyra/Skyra^{fit}, MAGNETOM Prisma/Prisma^{fit}, MAGNETOM Avanto^{fit}
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: November 20, 2017
Received: November 21, 2017

Dear Mr. Fields:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K173592

Device Name
MAGNETOM Aera, MAGNETOM Skyra/Skyrafit, MAGNETOM Prisma/Prismafit, MAGNETOM Avantofit

Indications for Use *(Describe)*
The MAGNETOM systems are 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.

The MAGNETOM systems 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.

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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Section 5 510(k) Summary

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

I. General Information

Establishment Siemens Medical Solutions USA. Inc.

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Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared November 20, 2017

Manufacturer Siemens Healthcare GmbH
Henkestr. 127
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Registration Number: 3002808157

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Device Name MAGNETOM Aera, MAGNETOM Skyra / Skyra^{fit}, MAGNETOM Prisma / Prisma^{fit} and MAGNETOM Avanto^{fit} with *syngo* MR E11C - AP04 software

Trade Names	MAGNETOM Aera
	MAGNETOM Skyra
	MAGNETOM Skyra^{fit}
	MAGNETOM Avanto^{fit}
	MAGNETOM Prisma
	MAGNETOM Prisma^{fit}

Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	Class II
Product Code:	Primary: LNH, Secondary: LNI, MOS

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The indications for use for the subject device are the same as the predicate devices and are as follows:

The MAGNETOM systems are 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.
The MAGNETOM systems 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.

Device Description

MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/Prisma^{fit} with *syngo* MR E11C software were cleared with K153343 and MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} systems with *syngo* MR E11C software were cleared with K162102.

To address the new feature GOKnee3D and the modifications summarized in Section 3 and furthermore described in this Premarket Notification Siemens intends to make the software application package *syngo* MR E11C - AP04 available to the systems mentioned above.

The additional options for the *syngo* MR E11C software is being made available for the following MAGNETOM MR Systems:

- MAGNETOM Aera,
- MAGNETOM Skyra / Skyra^{fit}

- MAGNETOM Prisma / Prisma[fit]
- MAGNETOM Avanto[fit]

Those options include a new feature with a modified sequence and modified features for the above mentioned MR systems. A high level summary of sequences, features and improvements made available for the above systems is included below.

New Feature

– **GOKnee3D[2]**
GOKnee3D is a fast, push-button, clinically validated knee examination which comprises the AutoAlign knee localizer and two CAIPIRINHA SPACE sequences (PD and T2 fat suppression) to support fast high-resolution 3D exams of the knee

Modified Features

– **SPACE with CAIPIRINHA acquisition technique**
The 3D SPACE pulse sequence (K153343 for Aera, Skyra, Prisma /Prisma[fit]; K162102 for Avanto[fit] and Skyra[fit]) now offers the iPAT mode CAIPIRINHA (K153343 for Aera, Skyra, Prisma /Prisma[fit]; K162102 for Avanto[fit] and Skyra[fit])

– **Dual Monitor support**
To support the user with more efficient use of the Dot Cockpit and post-processing parallel to the examination, a second monitor will be offered

– **Compressed Sensing Cardiac Cine (BEAT _CS Sequence)**
With the *syngo* MR E11C - AP04 software, Compressed Sensing Cardiac Cine is made available for MAGNETOM Prisma and MAGNETOM Prisma[fit]. The Compressed Sensing Cardiac Cine was already described in K163312 for the *syngo* MR E11C - AP02 software and is used unchanged to this clearance

Technological Characteristics

MAGNETOM Aera, MAGNETOM Skyra/Skyra[fit], MAGNETOM Prisma/Prisma[fit] and MAGNETOM Avanto[fit] with *syngo* MR E11C - AP04 Software have the same technological characteristics as the predicate devices MR systems:

Predicate Devices	FDA Clearance Number	Product Code
Software *syngo* MR E11C_AP02 for MAGNETOM Aera, Skyra	K163312, cleared January 27, 2017	LNH, LNI, MOS
Software *syngo* MR E11C for MAGNETOM Prisma/Prisma[fit]	K153343, cleared April 15, 2016	LNH, LNI, MOS
Software *syngo* MR E11C for MAGNETOM Avanto[fit]/Skyra[fit]	K162102, cleared November 22, 2016	LNH, LNI, MOS

[2] Available only for MAGNETOM Aera and MAGNETOM Skyra

The subject devices are substantially equivalent to the predicate devices with regard to the hardware, operational environment, programming language, operating system and performance.

syngo MR E11C - AP04 software conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

syngo MR E11C - AP04 software includes new and modified features which are seen as substantially equivalent related to the predicate devices. Thus *syngo* MR E11C - AP04 for MAGNETOM Aera, MAGNETOM Skyra/Skyra^{fit}, MAGNETOM Prisma/Prisma^{fit} and MAGNETOM Avanto^{fit} has the same technological characteristics as the predicate device systems.

Nonclinical Tests

- The following performance testing was conducted on the subject devices for the modified sequence (CAIPIRINHA SPACE). Sample clinical images were taken for particular migrated modified sequence when determined to be necessary.
- Image quality assessments of the new sequence and algorithms were completed.
- 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”

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

Clinical Tests

No clinical tests were conducted to support the subject devices and the substantial equivalence argument; however, clinical images and LV evaluation were provided to support the argumentation and documentation which demonstrate the clinical utility and technical capabilities of the method.

Safety and Effectiveness

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

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 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 software development, SW 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. Furthermore, the operators are healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

The *syngo* MR E11C - AP04 software for the MAGNETOM Aera, MAGNETOM Skyra/Skyra^{fit}, MAGNETOM Prisma/Prisma^{fit} and MAGNETOM Avanto^{fit} conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

Substantial Equivalence

syngo MR E11C - AP04 software for the MAGNETOM Aera, MAGNETOM Skyra/Skyra^{fit}, MAGNETOM Prisma/Prisma^{fit} and MAGNETOM Avanto^{fit} includes new and modified features compared to the predicate devices shown below. Hardware is identical to the cleared MAGNETOM scanners in the predicate devices.

Predicate Devices Information

Predicate Devices	FDA Clearance Number	Product Code	Manufacturer
Software *syngo* MR E11C_AP02 for MAGNETOM Aera, Skyra	K163312, cleared January 27, 2017	LNH, LNI, MOS	Siemens Healthcare GmbH
Software *syngo* MR E11C for MAGNETOM Prisma/Prisma^{fit}	K153343, cleared April 15, 2016	LNH, LNI, MOS	
Software *syngo* MR E11C for MAGNETOM Avanto^{fit}/Skyra^{fit}	K162102, cleared November 22, 2016	LNH, LNI, MOS	

Recall Information

The predicate device(s) have not been subject to design-related recalls.

Conclusion as to Substantial Equivalence

MAGNETOM Aera, MAGNETOM Skyra/Skyra^{fit}, MAGNETOM Prisma/Prisma^{fit} and MAGNETOM Avanto^{fit} with *syngo* MR E11C - AP04 software, have the same intended use and different technological characteristics as the predicate devices with respect to the magnetic resonance features and functionalities. The MR system hardware (i.e. scanner, coils, etc.) remains unchanged. The conclusions from the non-clinical data suggest that the features with different technological characteristics from the subject devices bear an equivalent safety and performance profile as that of the predicate devices. Therefore the subject devices are substantially equivalent to the predicate devices.