DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Cordell Fields, Esq.
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

September 29, 2015

Re: K151579
Trade/Device Name: MAGNETOM Aera (24-channel), MAGNETOM Avantofit, MAGNETOM Skyrafit, MAGNETOM Prisma/ Prismafit
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: August 28, 2015
Received: August 31, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151579

Device Name

MAGNETOM Aera (24-channel), MAGNETOM Avantofit, MAGNETOM Skyrafit, MAGNETOM Prisma/ Prismafit

Indications for Use *(Describe)*

The MAGNETOM systems are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display 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 described above 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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Registration Number 2240869

Date Prepared June 9, 2015

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Device Name Syngo MR E11 for MAGNETOM Aera (24) (1.5T), MAGNETOM Avanto^{fit} (1.5T), MAGNETOM Skyra^{fit} (3T) and MAGNETOM Prisma/Prisma^{fit} (3T)

Trade Names:
MAGNETOM Aera
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 MAGNETOM systems [MAGNETOM Aera, MAGNETOM Skyra^{fit}, MAGNETOM Avanto^{fit}, MAGNETOM Prisma and MAGNETOM Prisma^{fit}] 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

The subject device, *syngo* MR E11B system software, is being made available for the following MAGNETOM MR Systems:

- MAGNETOM Aera (24-channel configuration),
- MAGNETOM Avanto^{fit},
- MAGNETOM Skyra^{fit},
- MAGNETOM Prisma and
- MAGNETOM Prisma^{fit}

Two new coils, Body 30/60 and Body 6 long, will be available for the subject device systems. The feature FREEZEit will be extended to other body regions. In addition to the abdomen region, FREEZEit will be extended to other regions such as the head, head and neck, pelvis, and chest region. . The syngo MR E11B SW also includes new sequences as well as minor modifications of already existing features. A high level summary of the new sequences can be viewed below:

DSI

With software version syngo MR E11B Siemens offers DSI for MAGNETOM Prisma, Prisma^{fit} and Skyra^{fit} systems. The DSI option allows diffusion-weighted images to be acquired according to a DSI-compatible q-space sampling scheme.

DSI is based on sampling the “q-space”, where “q-space” is defined in analogy to the “k-space” by the moment of the diffusion encoding gradients **G**: $\mathbf{q} = \gamma/2\pi \int \mathbf{G}(t)\, dt$.

While the Fourier transform of k-space data generates the image content, a Fourier transform of q-space data allows calculating a probability density function. This data provides information about the probability of a particle moving to a certain position in space within a certain time interval by diffusive motion.

The DSI Application is only available for MAGNETOM Prisma/Prisma^{fit} and Skyra^{fit} Systems.

QISS evaluation

QISS (Quiescent-Interval Single-Shot) MR Angiography is a technique for non-contrast-enhanced MR Angiography (non-CEMRA) that is particularly suited for examinations of patients with PAD. Since patients with PAD may also suffer from additional impairments such as renal dysfunction, the administration of contrast agent may often be unadvisable in this patient group. Siemens provides a manageable and optimized QISS workflow for imaging peripheral arteries, which can be easily adapted by the customer based on the patient’s needs.

A new “Dot Engine” is provided to ease MRI acquisitions in Radiation Therapy.

RT Dot Engine

RT Dot Engine is a new Dot Engine for aiding in Radiation Therapy planning. The RT Dot Engine does not provide new functionality, but collects and displays existing system information for the user. The RT Dot Engine comprises existing protocols, enhanced with the RT Planning Dot Add-in and the “MPR Planning” interaction step.The RT (Radiation Therapy) Dot Engine is used to ease MRI acquisitions of the head and the head/neck region with stereotactic frames or mask-based fixation techniques. RT Dot Engine is a workflow solution for acquiring MR images intended to aid in Radiation Therapy Planning. RT Dot engine helps streamline acquisition of MR images to be used along with any RT planning software that uses MR images in addition to CT images.

Technological Characteristics

SW *syngo* MR E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto^{fit}, MAGNETOM Skyra^{fit}, MAGNETOM Prisma and MAGNETOM Prisma^{fit} has the same technological characteristics as the predicate device systems (K141977; cleared November 19, 2014).

SW *syngo* MR E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] is substantially equivalent with regard to acquiring MR images steps/features.

The *syngo* MR E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] is substantially equivalent with regard to operational environment, programming language, operating system and performance.

syngo MR E11 for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit], conform to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

While *syngo* MR E11B offers additional capabilities with respect to the predicate device systems, the *syngo* MR E11B software on the subject device MR Systems has the same technological characteristics as the predicate device systems (K141977; cleared November 19, 2014).

Nonclinical Tests

The following performance testing was conducted on *syngo* MR E11B SW subject device:

- The coils were tested for SNR, image uniformity, and heating.
- Dedicated phantom testing was conducted on particular new sequences.
- Acoustic noise measurements were performed for quiet sequences
- Image quality assessments of all new/modified sequences and algorithms, were completed. In some cases a comparison of the image quality was made between the new/modified features and the predicate features.

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.

Clinical Tests

No clinical tests were conducted to support the subject device and the substantial equivalence argument; however, clinical images were provided to support the new coils as well as the new software features of the subject device.

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 device.

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 E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] conform 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 E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] includes all of the features of the predicate device, systems MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11A.

Predicate Device Information

Predicate Device Name	***FDA Clearance Number and Date***	***Product code***	***Manufacturer***
syngo MR E11A for the MAGNETOM systems Aera/Skyra	K141977, cleared November 19, 2014	LNH LNI,MOS	Siemens Healthcare GmbH

Reference Device Information

Reference Device Name	***FDA Clearance Number and Date***	***Product code***	***Manufacturer***
MAGNETOM Aera with *syngo* MR D13E	K132951 cleared at 15 November, 2013	Primary LNH	Siemens Healthcare GmbH

Reference Device Name	*FDA Clearance Number and Date*	*Product code*	*Manufacturer*
MAGNETOM Avanto[fit] and MAGNETOM Skyra[fit]	K130885 cleared at 17 May, 2013	Primary LNH	Siemens Healthcare GmbH
MAGNETOM Prisma and MAGNETOM Prisma[fit]	K132119 cleared at 22 November, 2013	Primary LNH	Siemens Healthcare GmbH

Conclusion as to Substantial Equivalence

syngo MR E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] has the same intended use and the same basic technological characteristics as the predicate device, systems MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR E11A, with respect to the magnetic resonance features and functionalities.

MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] with software *syngo* MR E11B will be used for acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra.)

The differences between the MR systems with the subject device software and the predicate device SW, including the aforementioned new software and hardware options, give the subject device the same capabilities as the predicate device systems. While there are some minor technical features that vary with respect to the predicate device MR Systems, the conclusions from the non-clinical data suggest that the features with different technological characteristics from the predicate device bear an equivalent safety and performance profile as that of the predicate and reference devices.

syngo MR E11B for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto fit, MAGNETOM Skyra fit, MAGNETOM Prisma and MAGNETOM Prisma[fit] is similar to the functionalities of the predicate device, and does not introduce any new issues of safety or effectiveness.

Therefore, Siemens is of the opinion that *syngo* MR E11 for MAGNETOM Aera (24-channel configuration), MAGNETOM Avanto[fit], MAGNETOM Skyra[fit], MAGNETOM Prisma and MAGNETOM Prisma[fit] does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed device

MAGNETOM Aera/ Skyra with software *syngo* MR E11A (K141977 cleared on November 19, 2014).