



Food and Drug Administration
10903 New Hampshire Avenue
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Siemens Medical Solutions, Inc.
% Mr. John Urtz
Regulatory Affairs Specialist
40 Liberty Boulevard Mail Code 65-1A
MALVERN PA 19355

April 15, 2016

Re: K153343

Trade/Device Name: MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma,
MAGNETOM Prisma^{fit}

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH

Dated: March 14, 2016

Received: March 14, 2016

Dear Mr. Urtz:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A large, semi-transparent "FDA" watermark is visible behind the signature.

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

Indications for Use

510(k) Number (if known)

k153343

Device Name

MAGNETOM Aera, MAGNETOM Skyra, 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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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. 40 Liberty Boulevard Mail Code 65-1A Malvern, PA 19355, USA Registration Number: 2240869
Date Prepared	April 13, 2016
Manufacturer	Siemens AG / Siemens Healthcare GmbH Henkestrasse 127 Erlangen Bayern, Germany 91052 Registration Number: 3002808157 SIEMENS SHENZHEN MAGNETIC RESONANCE LTD. Siemens MRI Center Hi-Tech Industrial park (middle) Gaoxin C. Ave., 2 nd Shenzhen 518057, P.R. CHINA Registration Number: 3004754211
Contact Person	Mr. John Urtz Regulatory Affairs Specialist Siemens Healthcare Siemens Medical Solutions USA, Inc. Customer Solutions Group 40 Liberty Boulevard Mail Code 65-1A Malvern, PA 19355, USA Phone: (610) 448-6002 Fax: (610) 640-4481
Device Name	<i>syngo</i> MR E11C software for MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/Prisma ^{fit} MR Systems

Trade Names: MAGNETOM Aera
MAGNETOM Skyra
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 device and are as follows:

The MAGNETOM systems [MAGNETOM Aera, MAGNETOM Skyra, 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 E11C system software, is being made available for the following MAGNETOM MR Systems:

- MAGNETOM Aera,
- MAGNETOM Skyra,
- MAGNETOM Prisma and
- MAGNETOM Prisma^{fit}

The *syngo* MR E11C SW includes new sequences, new features and minor modifications of already existing features. A high level summary of the new sequences and features is included below. Further, modified and migrated sequences and features are also listed.

New Sequences

- **qDWI - a new Quiet Diffusion Sequence for Brain Imaging**
A noise reduced sequence for diffusion weighted imaging (called “qDWI”) is provided with *syngo* MR E11C. The sequence is technically based on a readout segmented EPI sequence (RESOLVE, currently available on the predicate device software). Gradients have been stretched to minimize the slew rate in order to reduce acoustic noise.
- **Improvements in BLADE Imaging (fast TSE)**
With this software version, an optimized variant of the TSE for abdominal imaging is released and is called FAST_TSE. The main characteristics of FAST_TSE are the same as for TSE which is one of the most basic sequences available on all MAGNETOM Systems.

New Features

- **SMS EPI – a new feature for Brain Diffusion and BOLD Imaging**
In **Simultaneous Multi Slice** imaging several slices are excited simultaneously and separated during image reconstruction. The feature is intended for EPI diffusion and EPI BOLD brain imaging.
- **GOBrain – a new feature which supports brain examination in short acquisition time for MAGNETOM Aera/Skyra**
With *syngo* MR E11C a complete brain examination in short acquisition time is provided for MAGNETOM Aera and MAGNETOM Skyra systems with a 20, 32, or 64 channel head coil. The examination consists of a localizer, T1w, T2w, dark fluid (FLAIR), DWI, and T2*w protocol.
- **New features for Breast Dot Engine - Dynamic Breast Evaluation and Auto Bolus Detection**
With *syngo* MR VD13A (clearance K133435) the feature ‘Breast Dot Engine’, a workflow solution for breast MRI, was cleared. Following the FDA clearance of the contrast agent Gadavist® for breast MRI, this software version adds the Automatic Bolus Detection feature for support of contrast exams.

Modified Sequences or Features

- SPAIR fat sat improvements (applicable for 3T MR Systems addressed by *syngo* MR E11C)
- Improvements in Liver Segmentation
- Improvement in Multi Echo Dixon for Fat Iron Quantification

- A flow compensated SE sequence for 3T systems (Skyra and Prisma/Prisma^{fit}) only
- Improvements in Inline Ventricular function
- Improvements in VIBE

Migrated Features

- QISS, MyoMaps and LiverLab for MAGNETOM Skyra 24 only
- The Body 18 and Body 18 long coil will be made available for MAGNETOM Skyra (24-channel configuration only (“Skyra-24”). These coils are cleared on other Skyra systems with the primary predicate device with exception of Skyra-24.

Other Modifications

- Front cover panel refresh for MAGNETOM Aera and MAGNETOM Skyra
- Provide secure MR scanner setup for DoD (Department of Defense) Information Assurance compliance.

Technological Characteristics

Software *syngo* MR E11C for MAGNETOM Aera MAGNETOM Skyra, MAGNETOM Prisma and MAGNETOM Prisma^{fit} systems (“*syngo* MR E11C”) has the same technological characteristics as the predicate devices MR systems (K151579; cleared September 29, 2015 and K141977, cleared November 19, 2014).

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

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

While *syngo* MR E11C SW offers new and modified SW features, modified SW features with respect to the predicate device systems, the *syngo* MR E11C software on the subject device MR Systems has the same technological characteristics as the predicate device systems. Further, this submission includes hardware modifications including new coils for the Skyra-24 system (already cleared with other Skyra systems) and a cosmetic modification to the front cover panel for Aera and Skyra systems. These do not represent a change in technological characteristics.

Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images were taken for particular new and modified sequences.
- Acoustic noise measurements were performed for quiet sequences

- Image quality assessments of all new/modified sequences 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 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 E11C software for the MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma and MAGNETOM Prisma^{fit} systems, 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 SW for the MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma and MAGNETOM Prisma^{fit} Systems, includes all of the features of the primary predicate device and additional sequences and features as noted above.

Predicate Device Information

Primary Predicate Device	FDA Clearance Number and Date	Product code	Manufacturer
<i>syngo</i> MR E11B for MAGNETOM Aera (24) (1.5T), MAGNETOM Avanto ^{fit} (1.5T), MAGNETOM Skyra ^{fit} (3T) and MAGNETOM Prisma/ Prisma ^{fit} (3T)	K151597, cleared September 29, 2015	LNH LNI,MOS	Siemens AG / Siemens Healthcare GmbH
Secondary Predicate Device	FDA Clearance Number and Date	Product code	Manufacturer
Software <i>syngo</i> MR E11A for the MAGNETOM systems Aera/Skyra	K141977 cleared November 19, 2014	LNH LNI,MOS	Siemens AG / Siemens Healthcare GmbH

Conclusion as to Substantial Equivalence

syngo MR E11C software for the MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma and MAGNETOM Prisma^{fit} Systems has the same intended use and the same basic technological characteristics as the predicate device systems, MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma and MAGNETOM Prisma^{fit} Systems with *syngo* MR E11B, with respect to the magnetic resonance features and functionalities. 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 devices bear an equivalent safety and performance profile as that of the predicate and secondary predicate devices. Therefore the subject device is substantially equivalent to the predicate device.