



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

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

January 27, 2017

Re: K163312

Trade/Device Name: MAGNETOM Aera and MAGNETOM Skyra with syngo  
MR E11C – AP02 Software

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic resonance diagnostic device

Regulatory Class: II

Product Code: LNH, LNI, MOS

Dated: January 20, 2017

Received: January 23, 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.

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 over a large, semi-transparent watermark of the FDA logo.

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)  
K163312

Device Name  
MAGNETOM Aera & MAGNETOM Skyra

### Indications for Use (Describe)

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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

|                       |   |
|-----------------------|---|
| <b>Establishment</b>  | Siemens Medical Solutions USA. Inc.<br>40 Liberty Boulevard<br>Mail Code 65-1A<br>Malvern, PA 19355, USA<br><b>Registration Number:</b> 2240869   |
| <b>Date Prepared</b>  | November 22, 2016   |
| <b>Manufacturer</b>   | Siemens AG / Siemens Healthcare GmbH<br>Henkestr. 127<br>Erlangen Bayern, Germany 91052<br><b>Registration Number:</b> 3002808157<br><br>SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.<br>Siemens MRI Center<br>Hi-Tech Industrial park (middle)<br>Gaoxin C. Ave., 2 <sup>nd</sup><br>Shenzhen 518057, P.R. CHINA<br><b>Registration Number:</b> 3004754211 |
| <b>Contact Person</b> | Mr. Cordell L. Fields, Esq.<br>Regulatory Affairs Technical Specialist<br>Siemens Healthcare<br>Siemens Medical Solutions USA, Inc.<br>Customer Solutions Group<br>40 Liberty Boulevard<br>Mail Code 65-1A<br>Malvern, PA 19355, USA<br>Phone: (610) 448-6469<br>Fax: (610) 640-4481  |
| <b>Device Name</b>    | MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software   |
| <b>Trade Names</b>    | MAGNETOM Aera<br>MAGNETOM Skyra   |

**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:

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

### Device Description

MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C Software is cleared with K153343. To address the Compressed Sensing Cardiac Cine and the modified Software Features described in this Premarket Notification Siemens intends to make the Software Application Package syngo MR E11C - AP02 available to the MAGNETOM Aera and Skyra.

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

- MAGNETOM Aera,
- MAGNETOM Skyra

The additional Options for the MR Scanner Software syngo MR E11C include a new feature with a new 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 Sequence

- **Compressed Sensing Cardiac Cine (BEAT\_CS Sequence)**  
Within MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software, Compressed Sensing for Cardiac Cine is made available. To make this feature available a new sequence is introduced called BEAT\_CS which is based on a TrueFISP Sequence.

### New/Modified Features

- **SMS EPI for Breast, Abdomen, and Pelvis**  
In **S**imultaneous **M**ulti **S**lice imaging several slices are excited simultaneously and separated during image reconstruction. The feature is intended for EPI diffusion and EPI BOLD imaging and now available for Breast, Abdomen and Pelvis.
- **GOBrain+ for Gadolinium Enhanced Imaging**  
The GOBrain protocols available with syngo MR E11C (K153343) are adapted to support protocols designed and developed for use with gadolinium contrast agent to enhanced imaging of the brain

### Technological Characteristics

MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software has the same technological characteristics as the predicate device MR systems (K153343, cleared April 15, 2016).

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 - AP02 Software conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

*syngo* MR E11C - AP02 Software includes new features and a sequence which are seen as substantially equivalent related to the predicate devices. Thus *syngo* MR E11C - AP02 for Aera and Skyra has the same technological characteristics as the predicate device systems.

### Nonclinical Tests

- The following performance testing was conducted on the subject devices for the new sequence (BEAT\_CS). 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 - AP02 software for the MAGNETOM Aera and MAGNETOM Skyra 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 - AP02 software for the MAGNETOM Aera and MAGNETOM Skyra includes a new sequence and features compared to the predicate software *syngo* MR E11C. Hardware is identical to the cleared Aera and Skyra scanners in the predicate devices.

### Predicate Devices Information

| Predicate Devices                                      | FDA Clearance Number and Date   | Product code  | Manufacturer                         |
|--|---------------------------------|---------------|--------------------------------------|
| Software <i>syngo</i> MR E11C for MAGNETOM Aera, Skyra | K153343, cleared April 15, 2016 | LNH, LNI, MOS | Siemens AG / Siemens Healthcare GmbH |

## Conclusion as to Substantial Equivalence

*MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software*, has the same intended use and different technological characteristics as the predicate devices, *syngo MR E11C software*, with respect to the magnetic resonance features and functionalities. Further, 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.