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

November 19, 2014

Siemens Medical Solutions USA, Inc.
% Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway
MALVERN PA 19355

Re: K141977
Trade/Device Name: Software syngo MR E11A for the MAGNETOM systems Aera/Skyra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: October 31, 2014
Received: November 3, 2014

Dear Ms. Sookdeo:

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,

for

Janine M. Morris
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)*

K141977

Device Name
MAGNETOM Aera and MAGNETOM Skyra

Indications for Use *(Describe)*

The MAGNETOM systems described above 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 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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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. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA
Registration Number	2240869
Date Prepared	October 31, 2014
Manufacturer	Siemens AG Henkestrasse 127 D-91052 Erlangen, Germany Registration Number: 3002808157 SIEMENS SHENZHEN MAGNETIC RESONANCE LTD. Siemens MRI Center Hi-Tech Industrial park (middle) Gaoxin C. Ave., 2nd Shenzhen 518057, P.R. CHINA Registration Number: 3004754211
Contact Person	Ms. Nadia Sookdeo Regulatory Affairs Technical Specialist Siemens Healthcare Siemens Medical Solutions USA, Inc. Customer Solutions Group 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA Phone: (610) 448-4918 Fax: (610) 448-1787
Device Name	Software *syngo* MR E11A for the MAGNETOM systems Aera/Skyra
Trade Names:	MAGNETOM Aera MAGNETOM Skyra

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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

Predicate Device

Predicate Device Name	*FDA Clearance Number and Date*	*Product code*	*Manufacturer*
syngo MR D13A for the MAGNETOM systems Aera/Skyra(/Avanto/Verio)	K121434, cleared November 05, 2012	LNH LNI,MOS	Siemens AG

Reference Devices Thalassaemia Tools cleared with K073194 on February 14, 2008

Product	*FDA Clearance Number and Date*	Product code	Manufacturer
syngo MR D13A for the MAGNETOM systems Aera/Skyra(/Avanto/Verio)	K121434, cleared November 05, 2012	LNH LNI,MOS	Siemens AG
Tim TX True Shape and *syngo* MR D13C for MAGNETOM Skyra	K123510 cleared May 17, 2013	LNH	Siemens AG
Software update *syngo* MR D13A-AP-AA to *syngo* MR D13A for MAGNETOM Aera/Skyra	K132831 cleared November 01, 2013	LNH LNI,MOS	Siemens AG
MAGNETOM Aera/Skyra, *syngo* MR D13A with additional local coils	K133435 cleared December 12, 2013	LNH	Siemens AG
Thalassaemia Tools	K073194 cleared on February 14, 2008	LLZ	Cardiovascular Imaging Solutions Ltd.
syngo.MR Neurology	K121459 cleared June 22, 2012	LLZ, LNH	Siemens AG
syngo BreVis	K090038 cleared April 29, 2009	LNH	Siemens AG
"MAGNETOM Artis Combi Suite" for the MAGNETOM systems Aera/Skyra	K140253 cleared March 20, 2014	LNH, MOS	Siemens AG
MAGNETOM Spectra	K121160 cleared July 16, 2012	LNH, LNI,MOS	Siemens Shenzhen Magnetic Resonance Ltd.

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Product	*FDA Clearance Number and Date*	Product code	Manufacturer
MAGNETOM Aera with *syngo* MR D13E	K132951 cleared November 15, 2013	LNH	Siemens AG
Pediatric 16, a 1.5T Tim Coil/ Pediatric 16 a 3T Tim Coil for Aera/Skyra with *syngo* MR E11A	K140998 cleared July 11, 2014	MOS	QED

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II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The MAGNETOM systems [MAGNETOM Aera and MAGNETOM Skyra] 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, software *syngo* MR E11A for MAGNETOM Aera and MAGNETOM Skyra offers two new applications, LiverLab (an application of non-invasive liver evaluation) and MyoMaps (an application designed to provide a means to generate pixel maps for myocardial MR relaxation times). In addition, software *syngo* MR E11A makes the Dot Cockpit available for the user to modify and create Siemens Dot Engine workflows in a very intuitive way which supplements some of the support of an application specialist. The software *syngo* MR E11A also includes new and modified sequences as well as minor modifications of already existing features. In addition, three additional coils are offered and some hardware components have been modified.

Siemens Medical Solutions, USA Inc., intends to market MAGNETOM Aera and MAGNETOM Skyra with new software, *syngo* MR E11A. While *syngo* MR E11A offers additional capabilities with respect to the predicate device, the MAGNETOM Aera and MAGNETOM Skyra have the same technological characteristics as the predicate device (K121434; Cleared November, 5, 2012).

Furthermore, Siemens Medical Solutions, USA Inc., intends to market a new configuration of the MAGNETOM Skyra with 24 receive channels with software *syngo* MR E11A.

The MAGNETOM Aera and MAGNETOM Skyra will be offered ex-factory (new production) as well as in-field upgrades for the currently installed MAGNETOM Aera and MAGNETOM Skyra systems. The new MAGNETOM Skyra configuration with 24 receive channels will be offered as an ex-factory option (new production).

Technological Characteristics

MAGNETOM Aera/Skyra with *syngo* MR E11A and the predicate devices are substantially equivalent with regard to acquiring MR images steps/features.

MAGNETOM Aera/Skyra with *syngo* MR E11A and the predicate devices are substantially equivalent with regard to operational environment, programming language, operating system and performance

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MAGNETOM Aera/Skyra with *syngo* MR E11A and MAGNETOM Aera/Skyra with software *syngo* MR D13A, conform to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

Nonclinical Tests

The following performance testing was conducted on the 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.
- Features of LiverLab was validated with volunteer as well as phantom scans, and synthetic raw data
- MyoMaps was tested on volunteers after ECG's were applied. MyoMaps was compared to Thalassaemia Tools in a 100 person study
- All other software features were verified and validated.

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 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 and modified 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 MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR E11A
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.

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Substantial Equivalence

MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR E11A are magnetic resonance diagnostic devices that include nearly all of the features of MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR D13A.

Predicate Device Name	*FDA Clearance Number and Date*	*Product code*	*Manufacturer*
syngo MR D13A for the MAGNETOM systems Aera/Skyra(/Avanto/Verio)	K121434, cleared November 05, 2012	LNH LNI,MOS	Siemens AG

Conclusion as to Substantial Equivalence

MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR E11A have the same intended use and the same basic technical characteristics as the predecessor devices, MAGNETOM Aera and MAGNETOM Skyra with *syngo* MR D13A, with respect to the magnetic resonance features and functionalities. MAGNETOM Aera/Skyra with software *syngo* MR E11A will be used for acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra). The predicate devices, MAGNETOM Aera/Skyra with software *syngo* MR D13A, are also capable of acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra).

The differences between the subject device and the predicate device, which include the aforementioned new and modified software and hardware features (mainly software), give the subject device greater capabilities than the predicate device. While there are some technological characteristics which vary with respect to the predicate device, the conclusions from the non-clinical data suggest that the features (of different technological characteristics with respect to the predicate device) bear an equivalent safety and performance profile as that of the predicate and reference devices.

MAGNETOM Aera/Skyra with software *syngo* MR E11A is similar to the functionalities of the predicate and reference devices, and does not introduce any new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Aera/Skyra with *syngo* MR E11A 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 D13A (K121434 cleared on November 5, 2012).