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
65 Valley Stream Parkway
MALVERN PA 19355

March 31, 2016

Re: K153447
Trade/Device Name: MAGNETOM Spectra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 17, 2016
Received: March 18, 2016

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)*

K153447

Device Name

MAGNETOM Spectra

Indications for Use *(Describe)*

The MAGNETOM Spectra 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.

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.
65 Valley Stream Parkway
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Malvern, PA 19355, USA

Registration Number

2240869

Date Prepared

November 24, 2015

Manufacturer

SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
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Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number: 3004754211

Siemens AG
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number: 3002808157

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Device Name

Software *syngo* MR E11M for the MAGNETOM Spectra

Trade Names:	MAGNETOM Spectra
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

Indicatons for Use

The MAGNETOM Spectra 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.

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 E11M for the MAGNETOM Spectra, is the latest software version for the Siemens MR MAGNETOM Spectra. It is modified based on the software version *syngo* MR E11A, which was cleared with K141977 on November 19, 2014. The software functionality and applications are based on *syngo* MR E11A except in technical instances where adaptations were needed to support the system specific hardware and optimize the sequence/protocols. System tests validating the aforementioned adapations are provided in Appendix 9.

Listed below are the **hardware updates** to the MAGNETOM Spectra systems with software *syngo* MR E11M:

- two new coils
  - Breast 18 (cleared with K133435 on December 12, 2013)
  - Pediatric 16 (cleared with K140998 on July 11, 2014)
- a modified MARS(Measurement and Reconstruction System)
- an updated MRAWP/MRWP(Syngo Acquisition Workplace/ Syngo Workplace) based on the new host platform
- minor hardware changes to the transmit unit

The MAGNETOM Spectra with software version *syngo* MR E11M will be offered ex-factory (new production) as well as in-field upgrades for the currently installed MAGNETOM Spectra systems.

Technological Characteristics

MAGNETOM Spectra with *syngo* MR E11M and the predicate device, MAGNETOM Spectra with syngo MR D12, are substantially equivalent with regard to acquiring MR images steps/features.

MAGNETOM Spectra with *syngo* MR E11M and the predicate device are substantially equivalent with regard to operational environment, programming language, operating system and performance.

MAGNETOM Spectra with *syngo* MR E11M and MAGNETOM Spectra with software *syngo* MR D12 both 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.
- 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 were conducted to support the subject device and the substantial equivalence argument, however clinical images were provided to support the new coils 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 Spectra with software *syngo* MR E11M 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. The standards conformed to are the following:

19-4	General	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-	ES60601-1:2005/(R)2012 and A1:2012	AAMI ANSI

		1:2005, MOD)		
19-1	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	60601-1-2 Edition 3:2007-03	IEC
12-207	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic	60601-2-33 Edition 3.0 2010-03	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-89	General	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability	60601-1-6 Edition 3.1 2013-10	IEC
13-8	Software	Medical device software - Software life cycle processes	62304 First edition 2006-05	IEC

Substantial Equivalence

While t new and modified software and hardware featuresgive the subject device greater capabilities than the primary predicate device, MAGNETOM Spectra with software *syngo* MR D12, these additional capabilities are currently cleared features of secondary predicate device, MAGNETOM Skyra with software *syngo* MR E11A. (K141977; November 19, 2014) We believe the subject device to be substantially equivalent to the predicate devices.

Predicate Device Name	**Clearance**	**Product code**	**Manufacturer**
MAGNETOM Spectra with *syngo* MR D12 (Primary Predicate)	K121160 cleared July 16, 2012	LNH, LNI,MOS	Siemens Shenzhen Magnetic Resonance Ltd.

Predicate Device Name	Clearance	Product code	Manufacturer
Siemens MAGNETOM Skyra with *syngo* MR E11A (Secondary Predicate)	K141977	LNH	Siemens Healthcare GmbH

Conclusion as to Substantial Equivalence

There are no changes to the Indications for Use for the subject device, compared to that of the predicate device MAGNETOM Spectra with software *syngo* MR D12.

While the updated software provides the user with additional capabilities compared to the primary predicate device,MAGNETOM Spectra with software version *syngo* MR D12, these software features have been cleared with secondary predicate device MAGNETOM Skyra with software *syngo* MR E11A (K141977; November 19, 2014). While these additions for the subject device offer additional functionality to the end user, all of these features, as mentioned above, have been previously cleared and can be compared to existing features in the subject device and reference device. The different technological characterisitics of the new software do not raise new questions of safety and effectiveness.

Therefore, Siemens believes that the subject device, software version *syngo* MR E11M for MAGNETOM Spectra, is substantially equivalent to the predicate devicesmentioned above.