DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 27, 2017

Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
65 Valley Stream Pkwy.
MALVERN PA 19355

Re: K163211
Trade/Device Name: MAGNETOM Sempra with syngo MR E11S
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: November 15, 2016
Received: November 16, 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,

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

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)*
K163211

Device Name
MAGNETOM Sempra with syngo MR E11S

Indications for Use *(Describe)*

The MAGNETOM Sempra 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 Sempra 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.

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

Establishment

Siemens Medical Solutions USA. Inc.
40 Liberty Boulevard
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared

November 15, 2016

Manufacturer

Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C. Ave., 2nd
Hi-Tech Industrial Park
518057 Shenzhen
China
Registration Number: 3004754211

Contact Person

Mr. Cordell L. Fields, Esq.
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) 448-6469
Fax: (610) 640-4481

Device Name:	MAGNETOM Sempra with *syngo* MR E11S
Trade name:	MAGNETOM Sempra
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD), Emission Computed Tomography System

Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1200 21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Codes:	LNI, MOS

II. Safety and Effectiveness Information Supporting Substantial Equivalence

The MAGNETOM Sempra has the same intended use as the legally marketed predicate device, MAGNETOM Amira (K152283).

Intended Use

The MAGNETOM Sempra 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 Sempra 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, MAGNETOM Sempra (1.5T) with *syngo* MR E11S, is an MRI system that is substantially equivalent to the previously cleared predicate device MAGNETOM Amira with software version syngo MR E11N; K152283).

MAGNETOM Sempra is equipped with Tim4G + Dot technology and Siemens latest software platform *syngo* MR E11 which includes latest applications like Quiet Suite for quiet brain, spine and musculoskeletal exams, CAIPIRINHA for shorter breath-hold times and Advanced WARP which enables correction of in- through-plane distortions for better evaluation of soft tissue around metallic implants.

From the operational side, Brain, Spine and Large Joint Dot engines included in standard configuration of MAGNETOM Sempra deliver consistency in imaging of core body regions. The same software platform E11 would help users to shorten learning curve, plus the consistent result from Dot engines, MAGNETOM Sempra helps the user to get uniform quality. The Eco-Power technology is included and works by automatically switching off the cold head compressor during system standby or power off at night, and intelligently switching on/off of components between patients together with Zero Helium Boil-off technology to help customers to save operating cost.

MAGNETOM Sempra utilizes the similar design of hardware as the predicate device MAGNETOM Amira with *syngo* E11N (K152283), the main hardware changes are the modified Gradient Amplifier and introducing a new fixed patient table without vertical movement.

Technological Characteristics

The subject device, MAGNETOM Sempra with *syngo* MR E11S and the predicate device, MAGNETOM Amira with *syngo* MR E11N, are substantially equivalent with regard to acquiring MR images steps/features and with regard to the operational environment, programming language, operating system and performance.

The subject device, MAGNETOM Sempra with *syngo* MR E11S conforms 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

A clinical study of 34 individuals was conducted in accordance with IEC 60601-2-33 (Edition 3.1: 2013) to determine the nerve stimulation thresholds used to limit the gradient system output. The observed parameters were the PNS (Peripheral Nerve Stimulation) THRESHOLD LEVEL which are required in IEC 60601-2-33 (Edition 3.1:2013)

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.

MAGNETOM Sempra with Software *syngo* MR E11S, 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. The standards conformed to are the following:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General II (ES/EMC)	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 60601-1:2005, MOD)	ES60601-1:2005/(R)2012 and A1:2012,	AAMI ANSI
19-1	General II (ES/EMC)	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
12-271	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	60601-2-33 Ed. 3.1:2013	IEC
5-40	General I	Medical devices - Application of	14971 Second	ISO

	(QS/RM)	risk management to medical devices	Edition 2007-03-01	
5-89	General I (QS/RM)	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
13-32	Software/Informatics	Medical device software - Software life cycle processes	62304: 2006	AAMI ANSI IEC

Substantial Equivalence

The MAGNETOM Sempra with software *syngo* MR E11S is substantially equivalent to the following devices:

Predicate Device	FDA Clearance Number	FDA Clearance Date	Product Code
MAGNETOM Amira with software version *syngo* MR E11N	K152283	December 24, 2015	LNH, LNI, MOS

Reference Devices	FDA Clearance Number	FDA Clearance Date	Product Code
Software *syngo* MR E11C for the MAGNETOM System Aera	K153343	April 15, 2016	LNH, LNI, MOS
Software *syngo* MR D14 for the MAGNETOM ESSENZA (1.5T)	K130262	March 1, 2013	LNH

Conclusion as to Substantial Equivalence

MAGNETOM Sempra with Software *syngo* MR E11S has the same intended use as the predicate device MAGNETOM Amira (K152283, cleared on December 24,2015), with respect to the magnetic resonance features and functionalities.

MAGNETOM Sempra with Software *syngo* MR E11S will be used for acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra). The predicate device MAGNETOM Amira (K152283), is also capable of acquiring MR images (transverse, sagittal, coronal

and oblique cross sectional images, spectroscopic images and/or spectra). Though there are differences between the subject device and the predicate device, which include the new and modified software and hardware features, MAGNETOM Sempra with software *syngo* MR E11S has similar functionality as the predicate device, and does not introduce new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Sempra with Software *syngo* MR E11S does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device MAGNETOM Amira (K152283).