DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 18, 2016

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

Re: K161795
Trade/Device Name: MAGNETOM ESSENZA
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LNI, MOS
Dated: October 20, 2016
Received: October 21, 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)*
K161795

Device Name
MAGNETOM ESSENZA

Indications for Use *(Describe)*
The MAGNETOM ESSENZA is indicated for use as magnetic resonance diagnostic devices (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. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM ESSENZA 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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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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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.
65 Valley Stream Parkway
Mail Code 65-1A
Malvern, PA 19355, USA

Registration Number

2240869

Date Prepared

June 29, 2016

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 Healthcare GmbH
Henkestrasse 127
D-91052 Erlangen, Germany
Registration Number: 3002808157

Contact Person

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Device Name	Software *syngo* MR E11Q for the MAGNETOM ESSENZA
Trade Names:	MAGNETOM ESSENZA
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

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II. Safety and Effectiveness Information Supporting Substantial Equivalence

The subject device, MAGNETOM ESSENZA with *syngo* MR E11Q, has the same intended use and indications for use as the legally marketed predicate devices.

Indications for Use

The MAGNETOM ESSENZA with *syngo* MR E11Q is indicated for use as magnetic resonance diagnostic devices (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. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM ESSENZA 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 ESSENZA with software *syngo* MR E11Q, is the latest software version for the Siemens MR MAGNETOM ESSENZA. 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 SW and have been migrated from this previously cleared software. Only minor adaptations were needed to support the system specific hardware and to optimize the sequence/protocols, also to support the DGSU (Digital Gradient Small signal Unit) option for GPA (Gradient Power Amplifier).

Listed below are the **hardware updates** to the MAGNETOM ESSENZA system with software *syngo* MR E11Q:

- a modified MARS(Measurement and Reconstruction System), which is the same as the MaRS of MAGNETOM Amira system with software *syngo* MR E11N (K152283, cleared on December 24, 2015)
- an updated MRAWP (MR Syngo Acquisition Workplace), which is the same as the host platform of reference device MAGNETOM Amira with *syngo* MR E11N (K152283, cleared on December 24, 2015)
- a successor EOSC (Electrical Optical Signal Converter) of original COB (CAN Open Bridge)

The MAGNETOM ESSENZA with software version *syngo* MR E11Q will be offered ex-factory (new production) as well as in-field upgrades for the currently installed MAGNETOM ESSENZA systems.

A summary of the software feature updates to the MAGNETOM ESSENZA system with software *syngo* MR E11Q is provided below. All migrated features listed below have been cleared previously with K141977, K151579, and K152283.

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Migrated Software Features:

- MyoMaps
  - Provides quantitative information on tissue composition
- Quiet Suite
  - Provides sequences for quiet imaging
- 10-min Exam Dot Engine
  - 10 minute exams for the following regions: Head, L-spine, Knee, C-spine, Brain, Shoulder, Spine, T-spine, Hip, Extremities
- Spine Dot Engine
  - Delivers optimized cervical, thoracic and lumbar spine imaging
- Breast Dot Engine
  - Delivers optimized breast imaging
- Large Joint Dot Engine
  - Delivers optimized large joint imaging
- Neuro fMRI Package
  - Package consisting of 3D PACE, MR 3D Inline fMRI, and MR 3D Offline fMRI
- DTI Package
  - Allows for acquisition of data sets with multi-directional diffusion weighting to assess anisotropic diffusion properties of brain tissue
- Neuro Perfusion Package
- FREEZEit Body MRI Package
  - Facilitates high quality diagnostic MR imaging
- LiverLab
  - Non-invasive evaluation of liver fat and/or iron.
- BOLD 3D Evaluation
  - Provides features for clinical fMRI
- DTI Evaluation
  - Provides offline post-processing to generate and visualize parametric maps derived from the diffusion tensor to assess diffusion properties of brain tissue

Technological Characteristics
The subject device, MAGNETOM ESSENZA with *syngo* MR E11Q and the primary predicate device, MAGNETOM ESSENZA with syngo MR D14, 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 ESSENZA with *syngo* MR E11Q and MAGNETOM ESSENZA with software *syngo* MR D14 both conform to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

While there are some different technological characteristics such as some new and modified software applications, and hardware additions these differences have been tested and 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 devices.

Nonclinical Tests
The following performance testing was conducted on the subject device:

- All software features were verified and validated to ensure that they will perform as intended when in the clinical environment.
- Updated hardware MaRS, MRAWP and EOSC were tested in system and integration tests.

All functionality and performance have been tested in system and integration tests.

The results from each set of tests demonstrate that the device performs as intended and is therefore 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.

No animal testing has been performed on this 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 ESSENZA with software *syngo* MR E11Q 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 following standards are conformed to:

19-4	General	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical	ES60601-1:2005/(R)2012 and	AAMI ANSI

		electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	A1:2012	
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 the new and modified software and hardware features give the subject device greater capabilities than the primary predicate device, MAGNETOM ESSENZA with software *syngo* MR D14 (K130262; March 1, 2013), these additional capabilities are currently cleared features of secondary predicate device, MAGNETOM Aera with software *syngo* MR E11A. (K141977; November 19, 2014). Therefore, we believe the subject device to be substantially equivalent to the predicate devices.

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Predicate Device Name	Clearance	Product code	Manufacturer
MAGNETOM ESSENZA with *syngo* MR D14 (Primary Predicate)	K130262 cleared on Mar. 1, 2013	LNH	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Aera with *syngo* MR E11A (Secondary Predicate)	K141977 cleared on Nov. 19, 2014	LNH, LNI, MOS	Siemens Healthcare GmbH

Reference Device:

Reference Device Name	Clearance	Product code	Manufacturer
MAGNETOM Amira with *syngo* MR E11N	K152283 cleared on Dec 24, 2015	LNH	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Aera with *syngo* MR E11B	K151579 cleared September 29, 2015	LNH, LNI, MOS	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 legally marketed predicate device MAGNETOM ESSENZA with software *syngo* MR D14.

While the updated software provides the user with additional capabilities compared to the primary predicate device, MAGNETOM ESSENZA with software version *syngo* MR D14, these software features have been cleared with secondary predicate device MAGNETOM Aera with software *syngo* MR E11A (K141977, cleared on November 19, 2014). The different technological characteristics of the new software do not raise new questions of safety and effectiveness. All features have been tested and verified and validated to be effective.

Therefore, Siemens believes that the subject device, software version *syngo* MR E11Q for MAGNETOM ESSENZA, is substantially equivalent to the predicate devices mentioned above.