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.

January 27, 2017
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,

[Signature]

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

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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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
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Registration Number: 2240869

Date Prepared
November 15, 2016

Manufacturer
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Registration Number: 3004754211

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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
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 syn go MR E11S, is an MRI system that is substantially equivalent to the previously cleared predicate device MAGNETOM Amira with software version syn go MR E11N; K152283).

MAGNETOM Sempra is equipped with Tim4G + Dot technology and Siemens latest software platform syn go 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.
Section 5: 510(k) Summary

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:

<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Product Area</th>
<th>Title of Standard</th>
<th>Reference Number and date</th>
<th>Standards Development Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-271 Radiology</td>
<td>Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis</td>
<td>60601-2-33 Ed. 3.1:2013</td>
<td>IEC</td>
<td></td>
</tr>
<tr>
<td>5-40 General I</td>
<td>Medical devices - Application of</td>
<td>14971 Second</td>
<td>ISO</td>
<td></td>
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</tbody>
</table>
Section 5: 510(k) Summary

<table>
<thead>
<tr>
<th>(QS/RM)</th>
<th>Description</th>
<th>Edition</th>
<th>Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-32</td>
<td>Software/Informatics Medical device software - Software life cycle processes</td>
<td>62304: 2006</td>
<td>AAMI ANSI IEC</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>FDA Clearance Number</th>
<th>FDA Clearance Date</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNETOM Amira with software version <em>syngo</em> MR E11N</td>
<td>K152283</td>
<td>December 24, 2015</td>
<td>LNH, LNI, MOS</td>
</tr>
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<table>
<thead>
<tr>
<th>Reference Devices</th>
<th>FDA Clearance Number</th>
<th>FDA Clearance Date</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Software <em>syngo</em> MR E11C for the MAGNETOM System Aera</td>
<td>K153343</td>
<td>April 15, 2016</td>
<td>LNH, LNI, MOS</td>
</tr>
<tr>
<td>Software <em>syngo</em> MR D14 for the MAGNETOM ESSENZA (1.5T)</td>
<td>K130262</td>
<td>March 1, 2013</td>
<td>LNH</td>
</tr>
</tbody>
</table>

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).