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

February 6, 2017

Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Specialist
40 Liberty Blvd, Mail Code 65-1A
MALVERN PA 19355

Re: K163294
Trade/Device Name: syngo.MR General; syngo.MR Cardiology; syngo.MR Neurology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 21, 2016
Received: November 22, 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)*
k163294

Device Name
syngo.MR General; syngo.MR Cardiology; syngo.MR Neurology

Indications for Use *(Describe)*

The software comprising the syngo.MR post-processing applications is post-processing software/applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the syngo.MR post-processing applications have their own indications for use.

syngo.MR General is a syngo based post-processing software for viewing, manipulating and evaluating MR images.

syngo.MR Cardiology is a syngo based post-processing software for viewing, manipulating and evaluating MR cardiac images.

syngo.MR Neurology is a syngo based post-processing software for viewing, manipulating, and evaluating MR neurological images.

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.

Date of Summary Preparation: November 16, 2016

I. General Information

Importer / Distributor: Siemens Medical Solutions USA, Inc.
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Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	***syngo*.MR General** *syngo*.MR General contains several MR Radiology workflows and MR specific Evaluation features. It covers single and engine applications: • *syngo*.MR Reading • *syngo*.MR General Routine • *syngo*.MR Cardiac Reader • *syngo*.MR Composing • *syngo*.MR General Engine *syngo*.MR General Engine is the precondition for all other, advanced MR post-processing applications and Engines.
	***syngo*.MR Cardiology** *syngo*.MR Cardiology covers single and engine applications: • *syngo*.MR Cardiac 4D Ventricular Function • *syngo*.MR Cardiac Flow • *syngo*.MR Cardio Engine
	***syngo*.MR Neurology** *syngo*.MR Neurology covers single and engine applications: • *syngo.*MR Neuro Perfusion • *syngo.*MR Neuro Perfusion Mismatch • *syngo*.MR Neuro fMRI • *syngo*.MR Tractography • *syngo*.MR Neuro Perfusion Engine • *syngo.*MR Neuro 3D Engine
Classification Name:	Regulation Description: Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Device Classification:	Class II devices
Regulation number:	21 CFR § 892.2050

Data	Details
Product Code:	Primary: LLZ, Secondary: LNH

Data	Details
Trade name / Device Proprietary Name:	***syngo*.MR General** *syngo*.MR General contains several MR Radiology workflows and MR specific Evaluation features. It covers single and engine applications: • *syngo*.MR Reading • *syngo*.MR General Routine • *syngo*.MR Cardiac Reader • *syngo*.MR Composing • *syngo*.MR General Engine *syngo*.MR General Engine is the precondition for all other, advanced MR post-processing applications and Engines.
Trade name / Device Proprietary Name	***syngo*.MR Cardiology** *syngo*.MR Cardiology covers single and engine applications: • *syngo*.MR Cardiac 4D Ventricular Function • *syngo*.MR Cardiac Flow • *syngo*.MR Cardio Engine
Trade name / Device Proprietary Name	***syngo*.MR Neurology** *syngo*.MR Neurology covers single and engine applications: • *syngo*.MR Neuro Perfusion • *syngo*.MR Neuro Perfusion Mismatch • *syngo*.MR Neuro fMRI • *syngo*.MR Tractography • *syngo*.MR Neuro Perfusion Engine • *syngo*.MR Neuro 3D Engine

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The software comprising the *syngo*.MR post-processing applications is post-processing software/applications to be used for viewing and evaluating the

designated images provided by a magnetic resonance diagnostic device. All of the software applications comprising the *syngo*.MR post-processing applications have their own indications for use.

syngo.MR General is a *syngo* based post-processing software for viewing, manipulating and evaluating MR images.

syngo.MR Cardiology is a *syngo* based post-processing software for viewing, manipulating and evaluating MR cardiac images.

syngo.MR Neurology is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR neurological images.

Device Description

The *syngo.*MR post-processing applications are *syngo* based post-processing software/applications to be used for viewing and evaluating[1] MR images provided by a magnetic resonance diagnostic device and enabling structured evaluation of MR images.

With SMRVB20 there are some new features, improvements and changes within the *syngo*.MR post-processing applications.

Within *syngo*.MR General VB20 there are the following new features and improvements:

- Arithmetic tools (new): Addition, Division, Multiplication
- Motion Correction (Elastic) (new): A Motion Correction algorithm can be used to perform elastic motion correction for angiography series (pre/post) or within 4D Breast datasets.
- MR Combine feature (new): Composing is also available for axial series.
- MR Prostate workflow provides PI-RADS™ v2 reporting (improved)
- Harmonized MR Basic workflow (improved): Several basic workflows for routine reading are consolidated in one MR Basic workflow.
- MR Neurology workflow: The MR Neurology workflow merges the already cleared workflows of MR Head, MR Neuro Perfusion, and MR Neuro Dynamics.
- Easy Reading Layout in all workflows (improved): All workflows now include a viewing step with Easy Reading Layout.
- Improved result management (improved): Multiple export options for findings in the interactive Findings details dialog

[1] While viewing (i.e. assessing) of images from other vendors is always possible; for advanced post-processing applications, some of the post-processing steps may depend on information contained in private DICOM tags ,therefore evaluation and processing of images can´t be guaranteed for other vendors.

Within *syngo*.MR Cardiology VB20 there are the following new features and improvements:

- Volume Quantification Tool (new): Volume Quant provides the capability to evaluate lesion volumes in the myocardium.
- Improved Result Distribution (improvement): Segmentation images can be exported as a result series.

Within *syngo*.MR Neurology VB20 there are the following new features, changes and improvements:

- MR Neuro 3D workflow:
  - Offline BOLD (new): offers the capability to run the GLM evaluations on raw BOLD data to generate fMRI statistical maps.
  - Offline DTI (new): offers the capability to generate TENSOR data together with all other diffusion maps (including b0, ADC, TraceW, FA, AD, RD) from raw diffusion series.
  - DTI evaluation (new): offers quantitative evaluation of diffusion parameters (FA, RD, AD, ADC, …) using ROI, VOI, or voxels.
- Neuro-specific Mean Curve Tool (minor improvement): The application *syngo*.MR Neuro Dynamics described in K151353 (and cleared August 07, 2015) is only available within *syngo*.MR Neuro Perfusion (neuro-specific Mean Curve Tool), but no longer as a single application.

The *syngo*.MR Neuro Perfusion Engine Pro, described in K151353 (and cleared August 07, 2015), is therefore obsolete within SMRVB20, as all applications are already part of *syngo*.MR Neuro Perfusion Engine.

General Safety and Effectiveness Concerns

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. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluating and post-processing of MR images.

syngo.MR General, *syngo*.MR Cardiology and *syngo*.MR Neurology 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:

Rec.- No.	Product Area	Title of Standard	Ref.- No. & Date	Standards Development Organization
5-96	General	Medical devices - Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
5-40	General	Medical devices - application of risk management to medical devices	14971: 2007	ISO
13-32	Software	Medical device software - Software life cycle processes	62304:2006	AAMI ANSI IEC
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set PS 3.1-3.20 (2011)	PS 3.1 - 3.20 (2016)	NEMA

Substantial Equivalence

Each of the medical devices, *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Neurology, running with the herein described version SMRVB20 has the same Intended Use as the primary predicate device (see Table 1). The conclusions from the non-clinical data suggest that the additional features bear an equivalent safety and performance profile as that of the predicate device and also does not affect the Indications for use of it. Therefore *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Neurology are considered to be substantially equivalent to their primary predicate devices, which are current legally marketed devices.

Table 1: Predicate devices for *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Neurology

Primary Predicate Device	FDA Clearance	Product Code	for Medical Device *syngo*.x
syngo.MR Post-Processing Software (Version SMRVA16A)	K130749 cleared August 20, 2013	LLZ, LNH	MR General MR Cardiology
syngo.MR Post-Processing Software Version SMRVB10A	K151353 cleared August 07, 2015	LLZ, LNH	MR Neurology MR General

Secondary Predicate Device	FDA Clearance	Product Code	for Medical Device *syngo*.x
syngo MR E11C Software for Siemens MR Systems: MAGNETOM Aera (1.5T), MAGNETOM Skyra (3T) and MAGNETOM Prisma/Prisma^{fit} (3T)	K153343 cleared April 15, 2016	LNH, LNI, MOS	MR General MR Neurology
syngo.via (VB10)	K150843 cleared April 24, 2015	LLZ	MR General MR Cardiology MR Neurology

Conclusion as to Substantial Equivalence

The syngo.MR post-processing applications are intended for similar indications as cleared in their according primary predicate devices.

In summary, Siemens is of the opinion that the *syngo*.MR post-processing applications do not raise new questions of safety or effectiveness and are substantially equivalent to the currently marketed primary predicate devices:

- *syngo*.MR Post-Processing Software, version SMRVA16A (K130749 cleared August 20, 2013) for *syngo*. MR General and *syngo*.MR Cardiology
- *syngo*.MR Post-Processing Software, version SMRVB10A (K151353 cleared August 07, 2015) for *syngo*.MR Neurology and *syngo*.MR General

There is new added functionality for *the syngo.*MR post-processing applications. The differences give the devices greater capabilities than the predicates, but the Intended Use, the basic technological characteristics and functionalities remain the same.

Therefore, Siemens believes that the subject device, the *syngo*.MR post-processing applications *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Neurology, are substantially equivalent to their primary predicate devices listed above in **Table 1**.