K130749

SIEMENS

510(k) Summary: *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular

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: March 15, 2013

AUG 2 0 2013

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 includes *syngo.MR Reading*, *syngo.MR* Composing and *syngo.MR* General Engine. *syngo.MR* Composing and *syngo.MR* General Engine are sold separately.
	syngo.MR Cardiology *syngo.MR* Cardiology includes *syngo.MR* Cardiac 4D Ventricular Function and *syngo.MR* Cardiac Flow. The applications can be sold together as *syngo.MR* Cardio Engine.
	syngo.MR Vascular *syngo.MR* Vascular includes *syngo.MR* Vascular Analysis.
Classification Name:	Regulation Description: - Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Device Classification:	Class II devices
Regulation number:	21 CFR § 892.2050
Product Code:	Primary: LLZ, Secondary: LNH

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

The software comprising the *syngo.MR* post-processing applications are 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 Vascular is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR vascular images.

Device Description

syngo.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular are post-processing software / applications to be used for viewing and evaluating MR images provided by a magnetic resonance diagnostic device. *syngo*.MR General; *syngo*.MR Cardiology and *syngo*.MR Vascular is *syngo*.via-based software that enable structured evaluation of MR images.

syngo.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular comprise the following (please refer to **Table 1**).

Table 1: *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular and their content

Medical device / post-processing application	**covered single and engines applications**
syngo.MR General	***syngo*.MR Reading** enables reading of 2D, 3D and 4D MR data. ***syngo*.MR Composing (optional)** is an offline application for creation of full-format images from overlapping MR volume data sets acquired at multiple stages. ***syngo*.MR General Engine (optional)** extends *syngo*.via by adding software for professional and routine MR radiology usage. It includes workflows for dedicated MR examinations that load and structure examination results automatically into layouts including user support to make sure that no data is missed. *syngo*.MR General Engine contains several MR Radiology Workflows, MR Cardio-Vascular Workflows and MR Basic Evaluation features.
syngo.MR Cardiology	***syngo*.MR Cardiac 4D Ventricular Function** enables 4D ventricular function evaluation and processes MR cine images of the heart and generates quantitative results for physicians in the diagnostic process. ***syngo*.MR Cardiac Flow** enables cardiac flow evaluation and processes velocity-encoded MR images to evaluate blood flow dynamics e.g. in the heart and the great vessels. The application generates quantitative results for physicians in the diagnostic process. ***syngo*.MR Cardio Engine**

Table 1: *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular and their content

Medical device / post-processing application	covered single and engines applications
	contains: - *syngo*.MR Cardiac 4D Ventricular Function; - *syngo*.MR Cardiac Flow.
syngo.MR Vascular	***syngo*.MR Vascular Analysis** enables assessment / quantification of general vascular pathologies.

General Safety and Effectiveness Concerns

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Product risk management is accomplished through a process in compliance with ISO 14971:2009 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 magnetic resonance images.

syngo.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular 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.

Substantial Equivalence

syngo.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular are substantially equivalent to the following current legally marketed devices (please refer to **Table 2**):

Table 2: Predicate devices for *syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Product Code
MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Avanto and MAGNETOM Verio with *syngo* MR D13A	K121434	November 05, 2012	LNH
syngo.via	K123375	November 20, 2012	LLZ

Conclusion as to Substantial Equivalence

The *syngo.MR* post-processing applications are intended for similar indications as cleared in the predicate devices, as previously noted.

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 devices MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Avanto and MAGNETOM Verio with software *syngo* MR D13A (K121434 cleared on November 5, 2012) as well as *syngo*.via (K123375 cleared on November 20, 2012).

There are minor changes to the indications for use for the subject device, compared to that of the predicate devices MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Avanto and MAGNETOM Verio with software *syngo* MR D13A as well as *syngo*.via VA20A. The differences between the subject devices and the predicate devices include the aforementioned improved changes, adaption to the updated *syngo*.via basis platform and other enhancements. The differences give the devices greater capabilities than the predicate devices, but have same technological characteristics and functionalities as the predicate devices, and do not introduce any new issues of safety or effectiveness.

Therefore, Siemens believes that the subject devices, the *syngo.MR* post-processing applications, are substantially equivalent to the predicate devices listed above.

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

NADIA SOOKDEO
REGULATORY AFFAIRS TECHNICAL SPECIALIST
SIEMENS MEDICAL SOLUTIONS USA, INC.
51 VALLEY STREAM PARKWAY
MALVERN PA 19355

August 20, 2013

Re: K130749
Trade/Device Name: *syngo*.MR General; *syngo*.MR Cardiology; *syngo*.MR Vascular
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, LNH
Dated: July 24, 2013
Received: July 25, 2013

Dear Ms. Sookdeo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130749

Device Name: ***syngo*.MR General, *syngo*.MR Cardiology and *syngo*.MR Vascular**

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130749