SIEMENS Traditional 510(k) Submission for: *syngo*.MR Post-Processing Software

JUL 18 2014

510(k) Summary: *syngo*.mMR General

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: April 7, 2014

I. General Information

Importer / Distributor
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Registration Number: 2240869

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Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	syngo.mMR General (NEW Indications for Use) syngo.mMR General is available as single application.
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.mMR General is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR, PET, and CT images as well as MR-PET and CT-PET images.

Device Description

syngo.mMR General is a *syngo*.via-based post-processing software / application to be used for viewing and evaluating[1] MR images provided by a magnetic resonance diagnostic device and enabling structured evaluation of MR images.
syngo.mMR General comprises the following:

[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.

Table 1: *syngo*.mMR General and its content; new applications for this submission are denoted (New); all other applications are currently cleared.

Medical device / post-processing application	**covered single and engines applications**
syngo.mMR General	***syngo*.mMR General (NEW Indications for USE)** *syngo*.mMR General is a syngo based post-processing software for viewing, manipulating, and evaluating MR, PET, and CT images as well as MR-PET and CT-PET images.

General Safety and Effectiveness Concerns
Instructions for use are included within the device labeling which enables 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 MR images.

syngo.mMR General 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.

Substantial Equivalence
syngo.mMR General is substantially equivalent to the following current legally marketed device:

Table 2: Predicate device for *syngo*.mMR General

Predicate Device Name	**FDA Clearance Number**	**FDA Clearance Date**	**Product Code**
syngo.MR Post-Processing Software Version SMRVA16B	K133401	March 11, 2014	LLZ LNH

Conclusion as to Substantial Equivalence
The syngo.MR post-processing application is intended for similar indications as cleared in the predicate device.

In summary, Siemens is of the opinion that the syngo.MR post-processing application does not raise new questions of safety or effectiveness and are substantially equivalent

to the currently marketed device *syngo*.MR Post-Processing Software Version SMRVA16B (K133401 cleared on March 11, 2014).

There are minor changes to the indications for use for the subject device with regards to *syngo*.mMR General. The differences give the device greater capabilities than the predicate, but the technological characteristics and functionalities are similar.

Therefore, Siemens believes that the subject device, the syngo.MR post-processing application, is substantially equivalent to the predicate device listed above in **Table 2**.

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

July 18, 2014

SIEMENS MEDICAL SOLUTIONS USA, INC.
CORDELL FIELDS, ESQ.
51 VALLEY STREAM PARKWAY
MALVERN PA 19355

Re: K140897
Trade/Device Name: syngo.mMR General
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, LNH
Dated: June 18, 2014
Received: June 19, 2014

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,

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

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)*
K140897

Device Name
syngo.mMR General

Indications for Use *(Describe)*
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.mMR General is a syngo based post-processing software for viewing, manipulating, and evaluating MR, PET, and CT images as well as MR-PET and CT-PET 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

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.

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