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K133401
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SIEMENS

Traditional 510(k) Submission / Bundling 510(k) for:
syngo.MR Post-Processing Software (Version SMRVA16B)

510(k) Summary: *syngo*.MR Neurology, *syngo*.MR Oncology, *syngo*.MR BreVis and *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: November 5, 2013

I. General Information

Importer / Distributor
Siemens Medical Solutions USA, Inc.
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Mail Code D02
Malvern, PA 19355, USA

Registration Number: 2240869

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Device Name and Classification

Data	Details
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
	syngo.MR Oncology *syngo*.MR Oncology covers single and engine applications: • *syngo*.MR Onco • *syngo*.MR 3D Lesion Segmentation • *syngo*.MR Tissue4D • *syngo*.MR Onco Engine
	syngo.MR BreVis *syngo*.MR BreVis is available as single application.
	syngo.mMR General *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.MR Neurology is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR neurological images.
syngo.MR Oncology is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR oncological images.
syngo.mMR General is a *syngo* based post-processing software for viewing, manipulating, and evaluating MR, PET and MR-PET images.
syngo.MR BreVis is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. *syngo*.MR BreVis supports evaluation of dynamic MR data. Depending on the region of interest, contrast agents may or may not be used.
syngo.MR BreVis automatically registers serial patient motion to minimize the impact of patient motion and visualizes different enhancement characteristics in those areas that are within the scope of the indications for use of MRI FDA approved contrast agents (parametric image maps). Furthermore, it performs other user-defined post-processing functions such as image subtractions, multiplanar reformats and maximum intensity projections. The resulting information can be displayed in a variety of formats, including a parametric image overlaid onto the source image. *syngo*.MR BreVis can also be used to provide measurements of the diameters, areas and volumes.
Furthermore syngo.MR BreVis can evaluate the uptake characteristics of segmented tissues that are within the scope of the indications for use of MRI FDA approved contrast agents. *syngo*.MR BreVis is optimized for viewing breast MR studies, and it also displays images from a number of other imaging modalities, like digitized mammographic images.
The images by other imaging modalities displayed with *syngo*.MR BreVis must not be used for primary diagnostic interpretation. *syngo*.MR BreVis also includes the option to add annotations based on the American College of Radiology's BI·RADS (Breast Imaging Reporting and Data System). When interpreted by a skilled physician, *syngo*.MR BreVis provides information that may be useful in diagnosis. Patient management decisions should not be made based solely on the results of *syngo*.MR BreVis analysis.

Device Description

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

syngo.MR Neurology, *syngo*.MR Oncology, *syngo*.MR BreVis *and* *syngo*.mMR General 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 Neurology	***syngo*.MR Neuro Perfusion** allows the visualization of temporal variations in the dynamic susceptibility time series of MR datasets. ***syngo*.MR Neuro Perfusion Mismatch** calculates the difference between the DWI lesion (diffusion ROI) and the PWI lesion (perfusion ROI) areas. ***syngo*.MR Neuro fMRI** is a workflow-oriented visualization package for BOLD fMRI. It enables the visualization of task-related areas of activation overlaid onto 2D or 3D anatomical datasets, providing the spatial correspondence of BOLD results. ***syngo*.MR Tractography (NEW)** allows assessment of central nervous system structures through utilitzing 3D tractographic data derived from Diffusion Tensor Imaging. ***syngo*.MR Neuro Perfusion Engine** Contains: - *syngo*.MR Neuro Perfusion - *syngo*.MR Neuro Perfusion Mismatch ***syngo*.MR Neuro 3D Engine** Contains: - *syngo*.MR Neuro fMRI - *syngo*.MR Tractography
syngo.MR Oncology	***syngo*.MR Onco** is a image viewing, processing and reading software that allows for oncological MR image evaluation in a structured way. ***syngo*.MR 3D Lesion Segmentation** provides convenient volumetric evaluation of lesions and/or other structure of interest as well as a particularly useful tool for oncology applications.

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 Tissue4D (NEW)** is a postprocessing workflow which supports the physician in the reading of dynamic contrast-enhanced MR data sets. ***syngo*.MR Onco Engine** contains: - *syngo*.MR Onco - *syngo*.MR 3D Lesion Segmentation
syngo.MR BreVis	***syngo*.MR BreVis (NEW)** is a software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies.
syngo.mMR General	***syngo*.mMR General (NEW)** is a *syngo* based post-processing software for viewing, manipulating and evaluating MR, PET and MR-PET images.

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

Table 2: Predicate devices for *syngo*.MR Neurology, *syngo*.MR Oncology, *syngo*.MR BreVis and *syngo*.mMR General

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Product Code
syngo.MR Post-Processing Software Version SMRVA16A	K130749	August 20, 2013	LLZ LNH

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 device *syngo*.MR Post-Processing Software Version SMRVA16A (K130749 cleared on August 20, 2013).

There are minor changes to the indications for use for the subject devices, compared to that of the predicate device *syngo*.MR Post-Processing Software Version SMRVA16A. The differences between the subject devices and the predicate device include the aforementioned improved changes, adaption to the updated *syngo*.via basis platform and other enhancements. The differences give the device greater capabilities than the predicate device, but have same technological characteristics and functionalities as the predicate device, 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 device 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

Siemens Medical Solutions USA, Inc.
% Ms. Nadia Sookdeo
Regulatory Affairs Technical Specialist
51 Valley Stream Parkway
MALVERN PA 19355

March 11, 2014

Re: K133401
Trade/Device Name: syngo.MR *Neurology*, syngo.MR *Oncology*, syngo.MR *BreVis*, syngo.mMR *General*
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ, LNH
Dated: February 12, 2014
Received: February 18, 2014

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133401

Device Name
syngo.MR Neurology, syngo.MR Oncology, syngo.MR BreVis and syngo.mMR General

Indications for Use *(Describe)*
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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