510(k) Summary: *syngo*.MR Neurology

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: May 15, 2012

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 Neurology *syngo*.MR Neurology includes *syngo*.MR Neuro Perfusion Engine and *syngo*.MR Neuro fMRI. *syngo*.MR Neuro Perfusion Engine bundles the applications *syngo*.MR Neuro Perfusion and *syngo*.MR Neuro Perfusion Mismatch. Each application is also sold separately.

Data	Details
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:	LLZ, LNH

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended Use

syngo.MR Neurology is a software solution to be used for viewing and evaluation of Neuroperfusion MR images for the routine use in MR image viewing.

It is a *syngo.via* based software option with dedicated MR specific workflows and basic MR specific evaluation tools and thus supports interpretation and evaluation of examinations within healthcare institutions, for example in Radiology, Neuroradiology and Neurosurgery environments.

Device Description

syngo.MR Neurology is a post-processing software/application to be used for viewing and evaluating neurological MR images provided by a magnetic resonance diagnostic device. *syngo*.MR Neurology is a *syngo*.via-based software that enables structured evaluation of MR neurological images.

The medical device *syngo*.MR Neurology comprises *syngo*.MR Neuro fMRI (Neuro functional evaluation) and *syngo*.MR Neuro Perfusion Engine.
syngo.MR Neuro Perfusion Engine comprises *syngo*.MR Neuro Perfusion (Perfusion and Local as well as Global AIF (Arterial Input Function)) and *syngo*.MR Neuro Perfusion Mismatch (Perfusion-Diffusion Mismatch Evaluation). This bundling is done for purchase purposes. Each application can also be purchased separately.

- ***syngo*.MR Neuro Perfusion** enables: processing of brain perfusion datasets acquired with DSC imaging. It provides color display and calculation of perfusion maps based on Arterial Input Function (AIF) (relative Mean Transit Time (relMTT), relative Cerebral Blood Volume (relCBV), and relative Cerebral Blood Flow (relCBF)).

- ***syngo*.MR Neuro Perfusion Mismatch** performs a calculation of the area differences between perfusion-diffusion datasets.

- ***syngo*.MR Neuro fMRI** is a workflow-oriented visualization package for BOLD fMRI.

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.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, 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 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.MR Neurology is substantially equivalent to the following predicate devices (see Table 1):

Table 1: Predicate devices for *syngo*.MR Neurology

Predicate Device Name	FDA Clearance Number	FDA Clearance Date
syngo MR D11D for MAGNETOM Aera & MAGNETOM Skyra	K111242	November 23, 2011
syngo.x®[3]	K092519	August 27, 2009

Conclusion as to Substantial Equivalence
syngo.MR Neurology has a similar intended use and the same basic technical characteristics as the predecessor devices *syngo* MR D11D (on MAGNETOM Aera and MAGNETOM Skyra) and *syngo*.x, in regards to the specific neurological functionalities. *syngo*.MR Neurology will be used for post-processing neurological images (viewing, processing and reading). The predicate device, MAGNETOM Aera and MAGNETOM Skyra with software *syngo* MR D11D, is also capable of post-processing neurological images (viewing, processing and reading), in addition to acquiring the MR images. *syngo*.x is used as the basic software platform and is intended for post-processing, for example, viewing, manipulating, communicating and

[3] *syngo*.x® is a registered trademark of Siemens AG.

storing medical images. The differences between the subject device and the predicate devices, which include the aforementioned new software applications, give the subject device greater capabilities than the predicate devices, but have the same technological characteristics as the predicate devices, are similar to the functionalities of the predicate devices, and do not introduce any new issues of safety or effectiveness.

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

JUN 22 2012

Ms. Michelle L. Byrne
Regulatory Affairs Technical Specialist
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Re: K121459
Trade/Device Name: *syngo*.MR Neurology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 15, 2012
Received: May 17, 2012

Dear Mr. Ms. Byrne:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K121459

Indications for Use Statement

510(k) Number (if known) _____

Device Name: ***syngo*.MR Neurology**

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 Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation
and Safety

510(k) K121459