



Food and Drug Administration
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Cordell Fields, Esq.
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

August 7, 2015

Re: K151353

Trade/Device Name: syngo.MR Neurology and syngo.MR Oncology
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and LNH
Dated: May 1, 2015
Received: May 21, 2015

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.
Acting 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K151353

Device Name

syngo.MR Neurology and syngo.MR Oncology

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 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.

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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**510(k) Summary: *syngo*.MR Post-Processing Software
(*syngo*.MR Neurology & *syngo*.MR Oncology)**

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 28, 2015

I. General Information

Importer / Distributor: Siemens Medical Solutions USA, Inc.
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Registration Number: 2240869

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Device Name and Classification

Data	Details
Trade name / Device Proprietary Name:	<p><i>syngo</i>.MR Neurology</p> <p><i>syngo</i>.MR Neurology covers single and engine applications:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Neuro Perfusion • <i>syngo</i>.MR Neuro Perfusion Mismatch • <i>syngo</i>.MR Neuro fMRI • <i>syngo</i>.MR Tractography • <i>syngo</i>.MR Neuro Perfusion Engine • <i>syngo</i>.MR Neuro Perfusion Engine Pro (NEW) • <i>syngo</i>.MR Neuro 3D Engine • <i>syngo</i>.MR Neuro Dynamics (NEW) <hr/> <p><i>syngo</i>.MR Oncology</p> <p><i>syngo</i>.MR Oncology covers single and engine applications: <i>syngo</i>.MR Onco <i>syngo</i>.MR 3D Lesion Segmentation <i>syngo</i>.MR Tissue4D <i>syngo</i>.MR Onco Engine <i>syngo</i>.MR Onco Engine Pro (NEW) <i>syngo</i>.MR OncoCare (NEW)</p>
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.

Device Description

syngo.MR Neurology and *syngo*.MR Oncology are *syngo*.via-based post-processing software / applications to be used for viewing and evaluating² MR images provided by a magnetic resonance diagnostic device and enabling structured evaluation of MR images.

syngo.MR Neurology and *syngo*.MR Oncology comprise of the following:

² 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*.MR Neurology and *syngo*.MR Oncology and their 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
<i>syngo</i> .MR Neurology	<p><i>syngo</i>.MR Neuro Perfusion allows the visualization of temporal variations in the dynamic susceptibility time series of MR datasets.</p> <p><i>syngo</i>.MR Neuro Perfusion Mismatch calculates the difference between the DWI lesion (diffusion ROI) and the PWI lesion (perfusion ROI) areas.</p> <p><i>syngo</i>.MR Neuro fMRI is a workflow-oriented visualization package for BOLD³ 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.</p> <p><i>syngo</i>.MR Tractography allows assessment of central nervous system structures through utilizing 3D tractographic data derived from Diffusion Tensor Imaging.</p> <p><i>syngo</i>.MR Neuro Dynamics (NEW) allows the assessment and evaluation of various spots of cerebral lesions.</p> <p><i>syngo</i>.MR Neuro Perfusion Engine contains:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Neuro Perfusion • <i>syngo</i>.MR Neuro Perfusion Mismatch <p><i>syngo</i>.MR Neuro Perfusion Engine Pro (NEW Marketing Bundle) contains:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Neuro Perfusion Engine • <i>syngo</i>.MR Neuro Dynamics <p><i>syngo</i>.MR Neuro 3D Engine contains:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Neuro fMRI • <i>syngo</i>.MR Tractography

³ Blood Oxygenation Level Dependent Imaging

Medical device / post-processing application	covered single and engines applications
<p><i>syngo</i>.MR Oncology</p>	<p><i>syngo</i>.MR Onco is an image viewing, processing and reading software that allows for oncological MR image evaluation in a structured way.</p> <p><i>syngo</i>.MR 3D Lesion Segmentation provides convenient volumetric evaluation of lesions and/or other structure of interest as well as particularly useful tools for oncology applications.</p> <p><i>syngo</i>.MR Tissue4D is post-processing workflow which supports the physician in reading of dynamic contrast-enhanced MR data sets.</p> <p><i>syngo</i>.MR OncoCare (NEW) enables the physician to evaluate signal intensities in segmented regions of interest with the help of histograms and color maps as well as evaluation the change of time in typical lesion parameters like diameter or volume (trending).</p> <p><i>syngo</i>.MR Onco Engine contains:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Onco • <i>syngo</i>.MR 3D Lesion Segmentation <p><i>syngo</i>.MR Onco Engine Pro (NEW) contains:</p> <ul style="list-style-type: none"> • <i>syngo</i>.MR Onco Engine • <i>syngo</i>.MR OncoCare (new, see below)

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 Neurology and *syngo.MR* Oncology 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 and *syngo.MR* Oncology running with the herein described version VB10 has the same Intended Use as the predicate device (see Table 2). 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* Neurology and *syngo.MR* Oncology are considered to be substantially equivalent to the following current legally marketed device:

Table 2: Predicate device for *syngo.MR* Neurology and *syngo.MR* Oncology

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

Conclusion as to Substantial Equivalence

The *syngo.MR* post-processing applications *syngo.MR* Neurology and *syngo.MR* Oncology are intended for similar indications as cleared in the predicate device.

In summary, Siemens is of the opinion that the *syngo.MR* post-processing applications *syngo.MR* Neurology and *syngo.MR* Oncology do 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 is new added functionality for *syngo.MR* Neurology (*syngo.MR* Neuro Dynamics) and *syngo.MR* Oncology (*syngo.MR* OncoCare). The differences give the device greater capabilities than the predicate, 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* Neurology and *syngo.MR* Oncology, is substantially equivalent to the predicate device listed above in **Table 2**.