Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

April 19, 2018

Re: K180336
Trade/Device Name: syngo.MR Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ LNH
Dated: February 6, 2018
Received: February 7, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K180336

Device Name

syngo.MR Applications

Indications for Use *(Describe)*

syngo.MR Applications is a syngo based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra.

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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# Section 5 510(k) Summary

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: February 06, 2018**

## 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 Applications**<br>It covers single and engine applications:<br>• *syngo*.MR General<br>o *syngo*.MR Reading<br>o *syngo.*MR General Routine<br>o *syngo.*MR Cardiac Reader<br>o *syngo.*MR Composing<br>o *syngo.*MR General Engine[2]<br>• *syngo*.MR Cardiology<br>o *syngo*.MR Cardiac 4D Ventricular Function<br>o *syngo*.MR Cardiac Flow<br>o *syngo*.MR Cardio Engine<br>• *syngo*.MR Neurology<br>o *syngo*.MR Neuro Perfusion<br>o *syngo*.MR Neuro Perfusion Mismatch<br>o *syngo*.MR Neuro fMRI<br>o *syngo*.MR Tractography<br>o *syngo*.MR Neuro Perfusion Engine<br>o *syngo*.MR Neuro 3D Engine<br>• *syngo*.MR Oncology<br>o *syngo*.MR Onco<br>o *syngo*.MR 3D Lesion Segmentation<br>o *syngo*.MR Tissue4D<br>o *syngo*.MR Onco Engine<br>o *syngo*.MR Onco Engine Pro<br>o *syngo*.MR OncoCare<br>• *syngo*.BreVis<br>• *syngo*.mMR General<br>• *syngo*.MR Spectroscopy<br>o *syngo*.MR Spectro SVS<br>o *syngo*.MR Spectro CSI<br>o *syngo*.MR Spectro Extension<br>• syngo.MR Vascular<br>o *syngo*.MR Vascular Analysis |
| Classification Name: | Regulation Description:<br>Picture Archiving and Communication System (PACS) |

[2] *syngo*.MR General Engine is the precondition for all other, advanced MR post-processing applications and engines

| Data | Details |
|---|---|
| Classification Panel: | Radiology |
| Device Classification: | Class II devices |
| Regulation number: | 21 CFR § 892.2050 |
| Product Code: | Primary: LLZ, Secondary: LNH |

| Data | Details |
|---|---|
| Trade name / Device Proprietary Name: | ***syngo*.MR Applications**<br>It covers single and engine applications:<br>• *syngo*.MR General<br>o *syngo*.MR Reading<br>o *syngo.*MR General Routine<br>o *syngo.*MR Cardiac Reader<br>o *syngo.*MR Composing<br>o *syngo.*MR General Engine<br>• *syngo*.MR Cardiology<br>o *syngo*.MR Cardiac 4D Ventricular Function<br>o *syngo*.MR Cardiac Flow<br>o *syngo*.MR Cardio Engine<br>• *syngo*.MR Neurology<br>o *syngo*.MR Neuro Perfusion<br>o *syngo*.MR Neuro Perfusion Mismatch<br>o *syngo*.MR Neuro fMRI<br>o *syngo*.MR Tractography<br>o *syngo*.MR Neuro Perfusion Engine<br>o *syngo*.MR Neuro 3D Engine<br>• *syngo*.MR Oncology<br>o *syngo*.MR Onco<br>o *syngo*.MR 3D Lesion Segmentation<br>o *syngo*.MR Tissue4D<br>o *syngo*.MR Onco Engine<br>o *syngo*.MR Onco Engine Pro<br>o *syngo*.MR OncoCare<br>• *syngo*.BreVis<br>• *syngo*.mMR General<br>• *syngo*.MR Spectroscopy |

| Data | Details |
|---|---|
| | o *syngo*.MR Spectro SVS<br>o *syngo*.MR Spectro CSI<br>o *syngo*.MR Spectro Extension<br>• syngo.MR Vascular<br>o *syngo*.MR Vascular Analysis |

## II. Safety and Effectiveness Information Supporting Substantial Equivalence

### Intended Use

"*syngo*.MR Applications is a *syngo* based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra."

### Device Description

The *syngo.*MR Applications are *syngo* based post-processing software/applications to be used for viewing and evaluating[3] MR images provided by a magnetic resonance diagnostic device and enabling structured evaluation of MR images.

The *syngo*.MR Applications is a combination of eight (8) former separately cleared medical devices which are now handled as features / functionalities within *syngo*.MR Applications.

These functionalities are combined unchanged compared to their former cleared descriptions; of course some minor enhancements and improvements are made.

The *syngo*.MR Applications are *syngo*.via based MR data viewing, processing and reading software allowing MR image evaluation in a structured way and supporting convenient reading and / or evaluation of MR images and data.

[3] 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.

The table below shows the functionalities of the *syngo*.MR Applications:

| Single functionalities and engines | Description |
|---|---|
| ***syngo.*MR General** | |
| *syngo*.MR Reading | Enables reading of 2D, 3D, and 4D MR data.<br>Includes:<br>• Basic workflow<br>• Workflow customization<br>• Follow-up support<br>• Rescan handling<br>Context-specific reporting |
| *syngo.*MR General Routine | It extends *syngo*.via by adding dedicated worflows and tools for routine and advanced reading of MR examinations. Several workflows are provided like MR Neurology, MR Prostate Reading, MR Breast Reading, and MR Cardio-Vascular Reading workflows.<br>*syngo*.MR General Routine provides several MR Evaluation tools: Subtraction, MeanCurve, Image Filter, 2D/3D Distortion Correction. ADC and b-value tool (for extrapolated b-values), Multiplication, Division, Addition, Elastic Motion Correction.Workflow optimized report templates. |
| *syngo.*MR Cardiac Reader | With *syngo*.MR Cardiac Reader the Cardiac Reading step within the Cardiac Analysis Workflow is provided. The Cardiac Reading enables viewing and evaluating different kinds of cardiac images using the common tools. |
| *syngo*.MR Composing | *syngo*.MR Composing is a dedicated offline application for creation of full-format images from overlapping MR volume data sets acquired at multiple stages. It can be used to compose images in any of the other workflows. |
| *syngo*.MR General Engine[4] | *syngo*.MR General Engine contains:<br>• syngo.MR General Routine<br>• syngo.MR Cardiac Reader<br>*syngo*.MR General Engine is the precondition for all other, advanced MR post-processing applications and Engines. |
| ***syngo.*MR Cardiology** | |
| *syngo*.MR Cardiac 4D Ventricular Function | *syngo*.MR Cardiac 4D Ventricular Function processes MR cine images of the heart which enables users to generates quantitative results for physicians in the diagnostic process. The MR cardiac interactive reporting template is included. |

[4] *syngo*.MR General Engine is the precondition for all other, advanced MR post-processing applications and engines

| Single functionalities and engines | Description |
|---|---|
| *syngo*.MR Cardiac Flow | 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. The MR cardiac interactive reporting template is included. |
| *syngo*.MR Cardio Engine | *syngo*.MR Cardio Engine contains:<br>• *syngo*.MR Cardiac 4D Ventricular Function<br>*syngo*.MR Cardiac Flow |
| ***syngo*.MR Neurology** | |
| *syngo*.MR Neuro Perfusion[5] | Extends the MR Neurology workflow with advanced processing tools for the analysis of brain perfusion datasets and allows the assessment and evaluation of various spots of cerebral lesions. |
| *syngo*.MR Neuro Perfusion Mismatch | Extends the assessment of brain perfusion datasets with calculation of mismatch area and mismatch ratio between two different contrasts (for example diffusion and perfusion) to support therapy decisions. |
| *syngo*.MR Neuro fMRI | A workflow oriented visualization package for BOLD fMRI. It enables the visualization of task-related areas of activation overlayed onto 2D or 3D anatomical datasets, providing the spatial correspondence of BOLD results with cortical landmarks or brain lesions. Image-based registration and multi-contrast evaluation are also available. Functional and anatomical image data can be exported for surgical planning as DICOM datasets. |
| *syngo*.MR Tractography | Enables the representation of diffusion paths of the human brain based on diffusion tensor imaging. *syngo*.MR Tractography supports surgery planning and is suitable for neurophysiological research in relation to cortical networking and pathologies of the white matter. |
| *syngo*.MR Neuro Perfusion Engine | *syngo*.MR Neuro Perfusion Engine contains:<br>• *syngo*.MR Neuro Perfusion<br>• *syngo*.MR Neuro Perfusion Mismatch |
| *syngo*.MR Neuro 3D Engine | *syngo*.MR Neuro 3D Engine contains:<br>• *syngo*.MR Neuro fMRI<br>• *syngo*.MR Tractography |
| ***syngo*.MR Oncology** | |
| *syngo*.MR Onco | An image viewing, processing and reading software that allows for oncological MR image evaluation in a structured way. |

[5] The application *syngo*.MR Neuro Dynamics described in K151353 (and cleared August 07, 2015) is only available within *syngo*.MR Neuro Perfusion (neurospecific Mean Curve Tool), but no longer as single application. The *syngo*.MR Neuro Perfusion Engine Pro, described in K151353 (and cleared August 07, 2015), is therefore obsolete within SMRVB20, as all applications are already part of syngo.MR Neuro Perfusion Engine.

| Single functionalities and engines | Description |
|---|---|
| *syngo.*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. |
| *syngo*.MR Tissue4D | A post-processing workflow which supports the physician in reading of dynamic contrast-enhanced MR data sets. |
| *syngo*.MR OncoCare | 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). |
| *syngo.*MR Onco Engine | *syngo*.MR Onco Engine contains:<br>• *syngo*.MR Onco<br>• *syngo*.MR 3D Lesion Segmentation |
| *syngo.*MR Onco Engine Pro | *syngo*.MR Onco Engine Pro contains:<br>• *syngo*.MR Onco Engine<br>• *syngo*.MR OncoCare |
| ***syngo.*MR BreVis** | |
| *syngo.*MR BreVis | A software package intended for use in viewing and analyzing magnetic resonance imaging (MRI) studies. |
| ***syngo.m*MR General** | |
| *syngo.m*MR General | A *syngo* based post-processing software for viewing, manipulating and evaluating MR, PET and MR-PET images. |
| ***syngo.*MR Spectroscopy** | |
| *syngo.*MR Spectro SVS | Provides evaluation of MR Single Voxel Spectroscopy (SVS) data with comprehensive workflow guidance. |
| *syngo.*MR Spectro CSI | Provides evaluation of MR Chemical Shift Imaging (CSI) data with comprehensive workflow guidance. *syngo*.MR Spectro CSI includes the possibility of an integrated reading of MR images and CSI spectroscopy data for prostate exams. |
| *syngo.*MR Spectro Extension | Provides access to advanced parameters, which allow the advanced user to configure the post processing and display of spectro results according to his / her personal needs. Both Single Voxel Spectroscopy (SVS) and Chemical Shift Imaging (CSI) data are supported. |
| ***syngo.*MR Vascular** | |
| *syngo.*MR Vascular Analysis | Enables assessment / quantification of general vascular pathologies. |

Except for the new product composition, there are some minor improvements and enhancements of the existing functionalities within the *syngo*.MR Applications.

Cardiac / Angio improvements:

- Improved functional analysis in the MR Cardiac Analysis workflow:
  - Mode for manual segmentation of the LV and RV
  - Pen tool for improved editing of LV and RV contours
  - Result values can be exported as text file
  - LV and RV contours can be saved and restored
- The workflows MR Angio SingleStation, MultiStation, TWIST and TimCT are consolidated into the new workflow MR Angiography

Additional minor improvements:

- 4D Navigation Toolbar
  - Mini-Toolbar for 4D navigation
  - Display of clinical phase labels
  - Easy navigation in mulit-phase data
- Freehand ROI for seed selection in Tractography
- Series Navigator: series numbers now displayed
- ADC / computed b-values: now as pre-processing
- Tissue4D Maps: color-bar added to image segment
- Median added to histogram statistics
- Relative frequency added to histogram
- Color-bar added to image segment (LUT)
- Wild card for series description
- Organ specific workflow

**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 Applications 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.

The standards conformed to are the following:

| Rec.- No. | Product Area | Title of Standard | Ref.- No. & Date | Standards Development Organization |
|---|---|---|---|---|
| 5-96 | General | Medical devices - Application of usability engineering to medical devices | 62366-1:2015 | AAMI ANSI IEC |
| 5-40 | General | Medical devices - application of risk management to medical devices | 14971: 2007 | ISO |
| 13-32 | Software | Medical device software - Software life cycle processes | 62304:2006 | AAMI ANSI IEC |
| 12-300 | Radiology | Digital Imaging and Communications in Medicine (DICOM) Set PS 3.1-3.20 (2011) | PS 3.1 - 3.20 (2016) | NEMA |

## Substantial Equivalence

The *syngo*.MR Applications VB30 has a different Intended Use as compared to the predicate devices. This is the result of the new product setup of combining the former eight (8) medical devices into one (1) device. However, the main functionalities of the former separate medical devices are used unchanged for syngo.MR Applications VB30, except for the aforementioned minor enhancements and improvements. The conclusions from the non-clinical data suggest that the additional features bear an equivalent safety and performance profile as that of the predicate devices and also does not affect the Indications for use of it. Therefore *syngo*.MR Applications are considered to be substantially equivalent to their primary predicate devices, which are current legally marketed devices.

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

| Predicate Device | FDA Clearance | Product Code |
|---|---|---|
| *syngo*.MR Post-Processing Software Version SMRVB20A | K163294 cleared February 6, 2017 | LLZ, LNH |
| *syngo*.MR Post-Processing Software Version SMRVB10A | K151353 cleared August 1, 2015 | LLZ,LNH |
| *syngo.*MR Spectroscopy | K120315 cleared April 13, 2012 | LLZ |
| *syngo*.MR Post-Processing Software Version SMRVA16A | K130749 cleared August 20, 2013 | LLZ,LNH |
| *syngo*.MR Post-Processing Software Version SMRVA16B | K133401 cleared March 11, 2014 | LLZ,LNH |

**Conclusion as to Substantial Equivalence**

The *syngo*.MR Applications are intended for similar indications as cleared in their according primary predicate devices.

In summary, Siemens is of the opinion that the *syngo*.MR Applications do not raise new questions of safety or effectiveness and are substantially equivalent to the currently marketed primary predicate devices as shown in **Table 1**.
Resulting from the new product setup of combining the eight (8) formerly cleared separate medical devices to one (1) medical device, the Intended Use changed. However, the main functionalities of the former devices will remain unchanged except for minor improvements and enhancements to give the device greater capabilities.

Therefore, Siemens believes that the subject device, the *syngo*.MR Applications is substantially equivalent to their primary predicate devices listed above in **Table 1**.