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

July 5, 2019

Re: K182904
Trade/Device Name: syngo.MR Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, LNH
Dated: June 5, 2019
Received: June 6, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K182904

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 510(k) Summary

This 510(k) 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.

Company: Siemens Medical Solutions USA, Inc.

40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: October 15, 2018

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Mail Code 65-1A
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

Manufacturing Sites:
Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen, Germany
Establishment Registration Number: 3002808157

2. Contact Person:

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3. Device Name and Classification:

Device Name	*syngo*.MR Applications
Trade Name	*syngo*.MR Applications: *syngo*.MR Brain Morphometry
Classification Name:	Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.2050
Device Class:	II
Primary Product Code:	LLZ
Secondary Product Code:	LNH

4. Legally Marketed Predicate Device:

Device Name	*syngo*.MR Applications SMRVB30A
510(k) Number:	K180336, cleared April 19, 2018
Classification Name:	Picture Archiving and Communication System (PACS)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.2050
Device Class:	II
Primary Product Code:	LLZ
Secondary Product Code:	LNH

5. Intended Use

The indications for use for the subject device are the same as the predicate device:

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.

6. Device Description:

The *syngo.*MR Applications are *syngo* based post-processing software/applications 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*.MR Brain Morphometry extends the MR Neurology workflow and offers a comprehensive package for the automatic calculation of the volume properties of different brain structures using MPRAGE datasets, which are typically acquired for a typical MR examination of the head.

With this premarket submission, the new functionality *syngo*.MR Brain Morphometry is introduced to extend the MR Neurology workflow that is a part of the formerly cleared medical device *syngo*.MR Applications (K180336).

7. Technological Characteristics

syngo.MR Applications with SMRVB30A offers a new feature, *syngo*.MR Brain Morphometry, compared to the predicate device *syngo*.MR Applications SMRVB30A (K180336; cleared April 19, 2018). While this is a feature that offers additional image viewing and evalution capabilities than the predicate device, the conclusions from all verification and validation data suggest that the feature bears an equivalent safety and performance profile to the predicate device.

The subject device is substantially equivalent to the predicate device with regard to the software, hardware, operational environment, programming language, operating system and performance.

syngo.MR Brain Morphometry for *syngo*.MR Applications SMRVB30A conforms to the standard for software medical devices (IEC 62304:2006), IEC as well as NEMA standards.

8. Nonclinical Tests

The following performance testing was conducted on the subject device:

- Software verification and validation testing was completed in accordance with the FDA guidance document, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" (May 11, 2005)

The following performance testing was conducted on the subject device:

- Performance of the new feature functionality was demonstrated by quantifying accuracy, repeatability and reproducibility of brain structure volume estimations by syngo.MR Brain Morphometry on a dataset of 1200 subjects, consisting of Alzheimer's patients (AD), mild cognitive impaired patients (MCI) and healthy controls (HC). The accuracy of the volumetric results was validated by comparing the automated results to a reference. Repeatability and reproducibility studies were conducted to demonstrate

[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, the evaluation and processing of images can´t be guaranteed for other vendors.

the robustness of volume measures estimated by syngo.MR Brain Morphometry with respect to both instrumental and patient noise within a single scanning session on one hand, and to significant changes to instrument, i.e., field strength and vendor as well as patient positioning, on the other hand. Acceptance criteria for performance tests were defined based on a literature review. In all validation experiments, syngo.MR Brain Morphometry passed the acceptance criteria. The correlation between the volumes estimated by syngo.MR Brain Morphometry and a reference device was 0.95 for grey matter, 0.80 for the hippocampus and 0.92 for white matter. The correlation of obtained volumes in the repeatability experiments was 0.96 for grey matter, hippocampus and white matter, 0.99 for the ventricular system. Volume correlation in the reproducibility experiments was 0.97 for grey matter, 0.94 for the hippocampus and 0.98 for white matter.

9. Clinical Tests

No clinical tests were conducted to test the performance and functionality of the new feature *syngo*.MR Brain Morphometry feature.

Verification and validation and a performance evaluation of the *syngo*.MR Applications SMR VB30A with the new feature *syngo*.MR Brain Morphometry has been performed and the new functionality has been validated for its intended use. The data from these activities were used to support the subject device and the substantial equivalence argument. Clinical publications are referenced to provide further information on the use and functionality of the feature.

No animal testing has been performed on the subject device and its new feature.

10. Safety and Effectiveness

syngo.MR Brain Morphometry extends the MR Neurology workflow which was cleared with the medical device *syngo*.MR Applications with software SMRVB30A (K180336) and is covered by the Intended Use of the *syngo*.MR Applications.

The conclusions from the non-clinical data suggest that the additional functionality bears an equivalent safety and performance profile to the predicate device (**Table 2**). Additionally, the indications for use remains the same.

Therefore, this workflow enhancement with *syngo*.MR Brain Morphometry is considered to be substantially equivalent to the predicate device *syngo*.MR Applications SMRVB30A.

syngo.MR Applications: *syngo*.MR Brain Morphometry 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 as stated in the following **Table 1**.

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-96	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
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 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA

Table 1: Standard requirements for *syngo*.MR Applications: *syngo*.MR Brain Morphometry

11. Substantial Equivalence and Conclusion

The *syngo*.MR Applications with software SMRVB30A including the new feature *syngo*.MR Brain Morphometry is substantially equivalent to the following predicate device (**Table 2**).

Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
syngo.MR Applications SMRVB30A	K180336	April 19, 2018	LLZ, LNH

Table 2: Predicate device for *syngo*.MR Brain Morphometry for *syngo*.MR Applications SMRVB30A

The subject device, *syngo*.MR Applications SMRVB30A, has been modified to include the new feature *syngo*.MR Brain Morphometry. No other modifications have been made.

syngo.MR Applications: *syngo*.MR Brain Morphometry has the same intended use and one different technological characteristic compared to the predicate device, *syngo*.MR Applications with SMRVB30A (K180336), with respect to the software features and functionalities. While the new feature varies with respect to the predicate device with expanded post-processing capabilities for the automatic calculation of the volume properties of different brain structures using MPRAGE datasets, the conclusions from all verification and validation data suggest that the feature bears an equivalent safety and performance profile to the predicate device. The new feature offers the user additional possibilities for the image viewing and evaluation. The modification aims to improve user workflow and reduce the complexity of the imaging procedure and does not change the intended use. The completed performance testing supports the substantial equivalence of the subject device to the predicate device.

In summary, *syngo*.MR Applications: *syngo*.MR Brain Morphometry has the same functionalities as the predicate device and, based on the aforementioned information, does not introduce new issues of safety or effectiveness. Therefore, Siemens is of the opinion that *syngo*.MR Applications: *syngo*.MR Brain Morphometry is substantially equivalent to the currently marketed device *syngo*.MR Applications with SMRVB30A (K180336).