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

January 31, 2020

Re: K192462
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: January 8, 2020
Received: January 9, 2020

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)*

K192462

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355, USA

Date Prepared: September 6, 2019

1. General Information

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

Manufacturer
Siemens Healthcare GmbH
Henkestrasse 127
Erlangen, Bayern, Germany 91052
Registration Number: 3002808157

2. Contact Information

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3. Device Name and Classification

Device Name: *syngo*.MR Applications
Trade Name: *syngo*.MR Applications
Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.2050
Classification: Class II

Product Code: Primary: LLZ, Secondary: LNH

4. Legally Marketed Predicate Device

Trade Name:	*syngo*.MR Applications SMRVB30A
510(k) Number:	K180336, cleared April 19, 2018
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.2050
Classification:	Class II
Product Code:	Primary: LLZ, Secondary: LNH

5. Intended Use

The indications for use for the subject device is 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

syngo.MR Applications with new software version SMR VB40A consists of the following enhancements and improvements to extend the different workflows and applications which are currently offered on the predicate device, *syngo*.MR Applications with SMRVB30A (K180336):

Enhanced functionality within the *syngo*.MR General application:

- Prostate Biopsy Support

Renaming and enhanced functionality within the *syngo*.MR Oncology application:

- *syngo*.MR OncoCare will be renamed to *syngo*.MR OncoTrend
- ADC-based whole-body diffusion evaluation

7. Technological Characteristics

The subject device, *syngo*.MR Applications with new software version SMR VB40A, is substantially equivalent to the predicate device with regard to the software, hardware, operational environment, programming language, operating system, and performance.

syngo.MR Applications with new software version SMR VB40A offers enhancements and improvements to the existing predicate device *syngo*.MR Applications SMRVB30A

(K180336). While these enhancements and improvements offer additional image viewing and evaluation capabilities compared to the predicate device, the conclusions from all verification and validation data suggest that these modifications bear an equivalent safety and performance profile to the predicate device.

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)
- Performance Evaluation of the described modifications were completed

The results from each set of tests demonstrate that the device performs as intended and is therefore substantially equivalent to the predicate device to which it has been compared.

9. Clinical Tests

No clinical tests were conducted to test the performance and functionality of the modifications introduced within *syngo*.MR Applications with software version SMRVB40A.
Verification and validation of the enhancements and improvements have been performed and these modifications have been validated for their intended use. The data from these activities were used to support the subject device and the substantial equivalence argument.
No animal testing has been performed on the subject device and its modifications.

10. Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to ensure safe and effective use of the device.

Risk management is ensured via ISO 14971:2007 compliance to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized in hardware and software development, testing, and product labeling.

Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

syngo.MR Applications with new software version SMR VB40A conforms to the following FDA recognized and international IEC, ISO and NEMA standards (Table 1):

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 2nd econd edition 2007-03-01	ISO
5-114	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 with SMR VB40A

11. Substantial Equivalence and Conclusion

syngo.MR Applications with new software version SMR VB40A is substantially equivalent to the following predicate device (Table 2):

Predicate Device	FDA Clearance Number and Date	Product code	Manufacturer
syngo.MR Applications SMR VB30A	K180336, cleared **April 19, 2018**	LLZ, LNH	Siemens Healthcare GmbH

Table 2: Predicate device for *syngo*.MR Applications with software version SMRVB40A

syngo.MR Applications with new software version SMR VB40A has the same intended use and basic technological characteristics compared to the predicate device, *syngo*.MR Applications with SMRVB30A (K180336), with respect to the software features and functionalities. While the new version SMRVB40A offers enhancements and improvements of the already cleared basic, neurological, oncological and cardiological workflows and applications, the conclusions from all verification and validation data suggest that the modifications bear an equivalent safety and performance profile to the predicate device. The enhancements and improvements offer additional possibilities for the image viewing and evaluation. The modifications aim to

improve user workflow and reduce the complexity of the imaging procedure and do not change the intended use.

In summary, *syngo*.MR Applications with new software version SMR VB40A has the same general 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 with new software version SMR VB40A is substantially equivalent to the currently marketed device *syngo*.MR Applications with SMRVB30A (K180336).

Siemens believes that *syngo*.MR Applications with new software version SMR VB40A is substantially equivalent to the currently marketed device *syngo*.MR Applications with SMRVB30A (K180336).