Siemens Medical Solution USA, Inc.
% Ms. Patricia D. Jones
Sr. Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
MALVERN PA 19355

September 12, 2019

Re: K190780
Trade/Device Name: syngo Application Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 9, 2019
Received: August 13, 2019

Dear Ms. Jones:

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)*

K190780

Device Name
syngo Application Software

Indications for Use *(Describe)*

The syngo Application Software is a medical software for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The syngo Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data.

Furthermore, the syngo Application Software can be deployed on systems of the Siemens Angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The syngo Application Software can also be combined with fluoroscopy systems or Radiographic systems.

The syngo Application Software can be configured with a variety of syngo or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: "*syngo* Application Software"

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

Date Prepared: September 11, 2019

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

1. General Information:

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

Manufacturing Site:
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355
Phone: (610) 448-6474
Email: patricia.d.jones@siemens-healthineers.com

3. Device Name and Classification:

Trade Name:	*syngo* Application Software
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	LLZ

4. Legally Marketed Predicate Device

Trade Name:	*syngo* Application Software

510(k) Clearance	K173611
Clearance Date	03/16/2018
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892. 2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	This predicate device has not been the subject of any design related recalls.

5. Device Description:

The "*syngo* Application Software" (VE2) is medical diagnostic software for real-time viewing, diagnostic review, image manipulation, optimization, communication, reporting and storage of medical images and data on exchange media. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. It can be deployed with a variety of *syngo* or Windows based software options, which are intended to assist the physician in evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens "*syngo* Application Software" (VE2) is designed to work with digital radiographic, fluoroscopic, interventional and angiographic systems.

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance to market the three new optional software features: **1)** *syngo* DynaCT Sine Spin; **2).***syngo* DynaCT Multiphase; and **3)** *syngo* Embolization Guidance. These new features will be added to the existing "*syngo* Application Software" (VD20) which was cleared in K173611 on 16/03/2018. These new software features are the subjects of this submission.

The "*syngo* Application Software" may be installed either on Siemens released PC hardware, on Siemens X-ray systems or on Siemens angiography systems.
The "*syngo* Application Software" (VE2) is within the same classification regulation and the intended use and the general Indications for Use Statement for Siemens' Picture Archiving and Communications System remains the same.

6. Indications for Use:

The *syngo* Application Software is a medical software for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and post processing and for viewing and post processing during interventional procedures.

The *syngo* Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data.

Furthermore, the *syngo* Application Software can be deployed on systems of the Siemens Angiography system family. It provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The *syngo* Application Software can also be combined with fluoroscopy systems or Radiographic systems.

The *syngo* Application Software can be configured with a variety of *syngo* or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available post-processing techniques and OEM options.

Procedures that can be performed includes minimally invasive surgical procedures and minimally invasive tumor treatment.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The subject device has the same intended use as the predicate device. Besides the proposed device modifications, the Subject Device has the same functionality and technology. Therefore the subject device is considered substantially equivalent to the commercially available Siemens' "*syngo* Application Software" (VD20).

All software components of the subject device are the same as the ones from the predicate device except for the new optional software applications as presented in the table below:

The table below provides comparison of the Subject Device modifications to the Predicate Device.

Modification	Subject Device *syngo* Application Software VE2	Predicate Device *syngo* Application Software VD20 (K173611)
syngo DynaCT *syngo* Sine Spin	This is a new feature with a spherical spiral trajectory with an additional sinusoidal movement component in Cran/Caud direction. The 3D trajectory starts with a Cran/Caud angle of zero, then goes to an angle of e.g. ten degrees in Cran direction, goes back to zero in the middle of the trajectory, then goes to	syngo DynaCT is an imaging software used to obtain CT like images. It allows the reconstruction of three-dimensional volume data (consisting of tomographic slices) out of two-dimensional projection images acquired with a standard angiographic C-arm device. It is also used for imaging both high contrast

Modification	Subject Device *syngo* Application Software VE2	Predicate Device *syngo* Application Software VD20 (K173611)
	ten degrees in Caud direction and back to Cran/Caud zero at the end of the trajectory. This allows better data coverage resulting less cone beam artifacts.	objects (vessels with iodine, bone) and soft tissue as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.
Comparison & Results	**Comparison:** The differences between the *syngo* DynaCT Sine Spin and syngo DynaCT is that the predicate device software feature does not have spherical spiral trajectory, which is an additional sinusoidal movement component in Cran/Caud direction. The reconstruction method is the same. **Results:** Bench test were conducted and were found acceptable and did not raise any new issues of safety or effectiveness. All software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.	
syngo DynaCT Multiphase	*syngo* DynaCT Multiphase can be used to assess the collateral status with time resolved DynaCT, depicting 10 different time points within a period of 60 seconds. These DynaCT runs can be utilized in the future for the generation of time resolved DynaCT angiograms:	*syngo* DynaCT uses a single spin to derive CT-like images. syngo DynaCT Cardiac with ECG triggering uses four consecutive DynaCT runs to optimize the image quality for cardiac imaging.
Comparison & Results	**Comparison:** The differences between the syngo DynaCT Multiphase and syngo DynaCT (cardiac) is that the predicate device allows two runs (typically one mask and one fill run) – four for DynaCT cardiac -The Subject Device feature allows ten consecutive runs which results in depicting 10 different time points within a period of 60 seconds. The reconstruction method is the same **Results:** Bench test were conducted and were found acceptable and did not raise any new issues of safety or effectiveness. All software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.	
syngo Embolization Guidance	The modified *syngo* Embolization Guidance in software VE2 allows the proximal point to be set by user, thus reducing automation, but increasing the applicability of *syngo* Embolization Guidance. The calculation method itself remains as in the predicate device. The algorithm was not changed.	*syngo* Embolization Guidance was introduced to determine automatically the feeder vessel for specific hepatic lesions, e.g. a tumor. Part of this automation relied on an automatic detection of the proximal point for the algorithm to know where to start the search for the feeder vessels.
Comparison & Results	**Comparison:** The differences between the modified *syngo* Embolization Guidance VE2 and the Predicate Device *syngo* Embolization Guidance is the modified version that allows the proximal point to be set by the user, thus reducing automation, but increasing the applicability of the feature. The Subject Device automatically detects the feeder vessel for specific hepatic lesions, e.g. a tumor. Part of this automation relied on an automatic detection of the proximal point for the algorithm to know where to start the search for the feeder vessels. **Results:** Bench test were conducted and were found acceptable and did not raise any new issues of safety or effectiveness. All software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.	

The Subject Device modifications do not alter the fundamental scientific technology from the 510(k) cleared predicate device Siemens' "*syngo* Application Software" (VD20), K173611

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the "*syngo* Application Software" (VE2) during product development.

Siemens claims conformance to the following performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-40	General	Medical devices - Application of risk management to medical devices	14971	2012	ISO
13-97	Software/ Informatics	Health software - Part 1: General requirements for product safety	82304-1	2017	IEC
13-32	Radiology	Medical Device Software - Software life-cycle process	62304 AC	2006 2008	AAMI ANSI IEC
5-114	General	Medical devices - Part 1 Application of usability engineering to medical devices	62366-1	2015	IEC
13-38	Software/ Informatics	Application of risk management for IT - networks incorporating medical devices - Part 1: Roles, responsibilities and activities	80001-1	2010	IEC

The modifications described in this Premarket Notification were supported with verification and validation testing.

Software Verification and Validation:

Software documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrates continued conformance with

special controls for medical devices containing software. Non-clinical tests were conducted on "*syngo* Application Software" (VE2) during product development.

The Risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

The Human Factor Usability Validation showed no safety relevant functions that need to be validated with a summative usability validation according to the IEC and FDA Guidelines. "*syngo* Application Software" (VE2) has been found to be safe and effective for intended users, uses and use environments through the design control verification and validation process. No further risk mitigations are necessary.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section is the required cybersecurity information.

Performance Verification/Validation & Test Report Summaries:
The Software features "*syngo* DynaCT Sine Spin", "*syngo* DynaCT Multiphase" and "*syngo* Embolization Guidance" performance functionality has been tested and validated. Verification and Validation testing in the form of Unit, Subsystem and System Integration testing as well as system validation testing were performed to evaluate the performance and functionality of the new features and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

All verification and validation data demonstrate that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.

The following bench testing was performed for the new features "*syngo* DynaCT Sine Spin", syngo Dyna3D High Speed and *syngo* DynaCT High Speed such as

- Homogeneity of reconstructed image
- Spatial Resolution
- Contrast to Noise Ratio
- Geometric Distortion

- Radiation Metrics CTDI, DAP
- Artifact analysis
- Gantry positioning accuracy
- z-direction Resolution (Reconstructed section thickness)

Bench testing was performed for the new feature syngo DynaCT Multiphase. A phantom study was performed to exclude a potential reduction in image quality over 10 runs.

Bench testing was performed for the modified feature “syngo Embolization Guidance”. The feeder detection algorithm was validated in a study of randomly selected clinical cases with the result that it is additionally suitable for prostate arteries.

The comparison of technological characteristic, non-clinical performance data, clinical images, Human Factor Usability data, and software validation data demonstrates that the Subject Device is as safe, and effective when compared to the Predicate Device that is currently marketed for the same intended use.

Siemens claims conformance to the following table of FDA Guidance Documents for this 510(k) submission.

FDA Guidance Document and Effective Date	
1.	Guidance for Industry and FDA Staff – **User Fees and Refunds for Premarket Notification Submissions 510(k)** Document issued on October 2, 2017
2.	Guidance for Industry and Food and Drug Administration Staff: **Refuse to Accept Policy for 510(k)s** Document issued on January 30, 2018
3.	Guidance for Industry and FDA Staff: **Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff** Document issued on August 12, 2005
4.	Guidance for Industry and Food and Drug Administration Staff: **The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]** Document Issued on July 28, 2014
5.	Guidance for Industry and FDA Staff: **Guidance for the Submission Premarket Notifications for Medical Image Management Devices** Document Issued on July 27, 2000
6.	Guidance for Industry and FDA Staff: **Guidance for the Content of Premarket Submission for Software in Medical Devices** Document issued on May 11, 2005
7.	Guidance for Industry and FDA Staff: **Guidance for Off-The-Shelf Software Use in Medical Devices** Document issued on September 9, 1999
8.	Guidance for Industry and FDA Staff: **Applying Human Factors and Usability Engineering to Medical Devices**. Document issued February 3, 2016
9.	Guidance for Industry and FDA Staff: **Pediatric Information for X-ray Imaging Device Premarket Notifications.** Document issued on November 28, 2017
10.	Guidance for Industry and FDA Staff: **Content of Premarket Submissions for**

FDA Guidance Document and Effective Date	
	Management of Cybersecurity in Medical devices. Document issued on October 2, 2014
11.	Guidance for Industry and FDA Staff: **Appropriate Use of Voluntary Consensus Standards in Premarket Submission for Medical Devices** Document issued on September 14, 2018

Summary of the performance Testing Data:
Performance tests were conducted to test the functionality of the "*syngo* Application Software" (VE2). These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing were found acceptable and do not raise any new issues of safety or effectiveness.

All software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.

9. 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 hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. Furthermore, the operators are health care professionals familiar with and responsible for the evaluating and post processing of medical images.

10. Conclusion as to Substantial Equivalence:
The predicate device "*syngo* Application Software" (VD20), K173611, was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that the subject device "*syngo* Application Software" (VE2) acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristic, non-clinical performance data, clinical images, and software validation data demonstrates that the subject device is as safe, and effective when compared to the predicate device that is currently marketed for the same intended