DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 9, 2017

Siemens Medical Solutions, USA, Inc.
Patricia Jones
Sr. Regulatory Affairs Specialist
40 Liberty Boulevard 65-1A
Malvern, Pennsylvania 19355

Re: K170747
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: May 11, 2017
Received: May 12, 2017

Dear Mrs. 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. 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,

For

Robert A. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170747

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.

510(k) Summary: "*syngo* Application Software" (VD20)

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

Date Prepared: May 11, 2017

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
Fax: (610) 640-4481
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	K163285
Clearance Date	02/14/2017
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	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" (VD20) is medical diagnostic software for real-time viewing, diagnostic review, post-processing, 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 the evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens "*syngo* Application Software" (VD20) is designed to work with digital radiographic, fluoroscopic, interventional and angiographic systems. The software platform with common software architecture, *syngo* application packages and basic services is the same as used with the "*syngo* Application Software" (VD20) cleared in K163285 with the exception of the added new software feature "*syngo* TrueFusion"

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance for the addition of a new software feature to the *syngo* Application Software.

Proposed Device Modifications:

1. Introduction of "*syngo* TrueFusion" software application for fusion of ultrasound information with 2D fluoroscopic images

2. Proposed new product claims associated with device

The "*syngo* Application Software" may be installed either on Siemens released PC hardware, on Siemens X-ray systems or on Siemens angiography systems. The combination of "*syngo* Application Software"

(VD20) and the Siemens released PC hardware will be marketed also as "syngo X Workplace".

The "*syngo* Application Software" (VD20) 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.

Proposed new product claims associated with "*syngo* TrueFusion"

Claim #	Feature /Component	Labeling Claim
1.	*syngo* TrueFusion	syngo TrueFusion – Add TEE guidance to live fluoroscopy with ease
2.	*syngo* TrueFusion	Navigate with improved anatomical orientation
3.	*syngo* TrueFusion	Integrated efficiency in TEE guidance
4.	*syngo* TrueFusion	Reduce complexity in challenging procedures
5.	*syngo* TrueFusion	Navigate with confidence through integrated TEE guidance
6.	*syngo* TrueFusion	Achieve automated co-registration with eSie Sync Automated probe detection in 2 single fluoro images and automated co-registration updates
7.	*syngo* TrueFusion	eSie Sync integrates co-registration efficiently in your workflow
8.	*syngo* TrueFusion	Probe detection enhanced by machine learning
9.	*syngo* TrueFusion	Hardware markers and probe model enable robust algorithm
10.	*syngo* TrueFusion	True integration of ACUSON SC2000 PRIME
11.	*syngo* TrueFusion	True integration and possibility to synchronize views enhances communication
12.	*syngo* TrueFusion	Share perspectives efficiently with view synchronization*
13.	*syngo* TrueFusion	Set landmarks swiftly with eSie Valves modeling
14.	*syngo* TrueFusion	Identify key anatomical landmarks with one-click eSie Valves modeling
15.	*syngo* TrueFusion	Assess valves and fuse model with live fluoroscopy at any time during the procedure
16.	*syngo* TrueFusion	Valve model reduced to the relevant structures on the fusion image for a clear view of your devices
17.	*syngo* TrueFusion	Annulus landmark overlay on live fluoroscopy can help find the perpendicular view.
18.	*syngo* TrueFusion	Target-oriented guidance through TEE structural information fusion
19.	*syngo* TrueFusion	More intuitive orientation through overlay of TEE cone on live fluoro*
20.	*syngo* TrueFusion	Claim Removed
21.	*syngo* TrueFusion	Claim Removed
22.	*syngo* TrueFusion	Direct real-time guidance from the ultrasound system
23.	*syngo* TrueFusion	syngo TrueFusion can shorten the learning curve in challenging procedures as it enables more intuitive anatomical orientation*

Claim #	Feature /Component	Labeling Claim
24.	*syngo* TrueFusion	Synchronization of TEE and angio image orientation allows to derive implantation angles from TEE.
25.	*syngo* TrueFusion	Assessment of valve morphology with eSie Valves™ modeling and fusion of relevant structures supports accurate device placement
26.	*syngo* TrueFusion	Dedicated probe design enables rapid and reliable registration updates**
27.	*syngo* TrueFusion	Reliable image fusion with dedicated probe design and eSie sync
28.	*syngo* TrueFusion	Target-oriented device navigation via True Volume TEE landmarks
29.	*syngo* TrueFusion	Direct export of fusion landmarks from the compatible ultrasound system.
30.	*syngo* TrueFusion	Overlay of TEE cone on live fluoro for greater intuition in orientation*
31.	*syngo* TrueFusion	Fast and reliable documentation with integrated patient co-registration from angiography and ultrasound systems
32.	*syngo* TrueFusion	C-arm angulation planning without fluoroscopy
33.	*syngo* TrueFusion	A confident clear view combined on one screen
34.	*syngo* TrueFusion	Facilitated communication through first-hand guidance from the modality expert
35.	*syngo* TrueFusion	Synchronized views can speed up orientation and communication*
36.	*syngo* TrueFusion	Synchronized views facilitating orientation / for a faster grasp of orientation*
37.	*syngo* TrueFusion	Claim Removed

**This is the result of individual user experience – results may vary*

***The quality of registration depends on the orientation of the probe, the angular difference between the two projections, the C-arm position, and the zoom stage.*

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 include: 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 software feature "*syngo* TrueFusion". The table below provides a comparison of the Subject Device modification to the Predicate Device.

Property	Subject Device syngo Application Software	Predicate Device syngo Application Software (K163285)	Comparison Results
SW VD20 New Software Application	Newly added software feature: *syngo* TrueFusion	"*syngo* TrueFusion" not available.	The new *syngo* TrueFusion software feature does not raise any new issues of safety of effectiveness. Validation and testing was conducted

The subject device modification does not alter the fundamental scientific technology from the 510(k) cleared predicate device Siemens' "*syngo* Application Software" (VD20), K163285.

8. Nonclinical Performance Testing:

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

Siemens claims conformance to the following performance standards:
Siemens claims conformance to the following performance standards:

- ISO 14971:2012
- IEC 60601-1-6:2010
- IEC 62304:2006 AC:2008
- IEC 62366-1:2015
- IEC 80001-1:2010

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

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 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 the "*syngo* Application Software" (VD20) during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of 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. The "*syngo* Application Software" (VD20) 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.

Summary of the performance testing data:
Performance tests were conducted to test the functionality of the "*syngo* Application Software" (VD20). These tests have been performed to assess the functionality of the subject device. Results of all conducted testing and

clinical assessments were found acceptable and did not raise any new issues of safety or effectiveness. Performance to *syngo* TrueFusion is provided below.

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.

Performance Verification/Validation & Test Report Summaries

Table 1: Validation Report Summary	
1.	Subject Device Modification:
	Added software feature “syngo TrueFusion”
2.	Objective or Purpose of Test:
	Validate syngo TrueFusion results
3.	Explanation of sample size and Statistical Methods:
	28 phantom test data sets
4.	Summary of Test Methodology:
	Multiple Measurements were performed from different directions of the C-arm by a board certified cardiologist.
5.	Explanation of Study Endpoints:
	All results are clinically accepted by a board certified radiologist.
6.	Explanation of Study Acceptance Criteria:
	Mean deviation shall not exceed 3mm with a standard deviation not exceeding 2mm.
7.	Test Report Results:
	Multiple Measurements were performed from different directions of the C-arm. The measurements show these mean and standard deviations from three different C-Arm positions (A, B, C): Experiment 1 position A mean 2,92mm with a standard deviation of 1,29mm, position B mean 2,59mm with a standard deviation of 1,50mm, position C mean 2,31mm with a standard deviation of 1,62mm, experiment 2 position A mean 2,76mm with a standard deviation of 1,31mm, position B mean 2,57mm with a standard deviation of 1,69mm, position C mean 2,13mm with a standard deviation of 1,48mm. The statistical significance – 80% successful experiments – is 0,0 for experiment 1 position A, 0,002 for B, 0,002 for C and 0,002 for experiment 2 position A, 0,015 for B and 0,002 for C. All results were clinically accepted by a board certified cardiologist.
8.	Supportive article reference(s) with explanation as for how it supports the modification:
	This is not applicable
9.	Conclusion Statement:
	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.

9. General Safety and Effectiveness Concerns:

Instructions for use are included in 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. To minimize electrical hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance 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), K163285, 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” (VD20) 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 use.