



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

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

November 16, 2016

Re: K162541
Trade/Device Name: syngo Application Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 3, 2016
Received: November 4, 2016

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. 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 yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a faint, large, light-blue watermark of the FDA logo.

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: January 31, 2017 See PRA Statement below.
510(k) Number (if known) K162541	
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 PRASStaff@fda.hhs.gov <i>"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."</i>	
FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (901) 443-6710 EF	

510(k) Summary: *syngo* Application Software

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

Date Prepared: November 3, 2016

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.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	K153346
Clearance Date	March 4, 2016
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 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 evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens *syngo* Application Software 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 (K153346).

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance for updated software features to the *syngo* Application Software.

Proposed Device Modifications:

1. Updated software feature *syngo* EVAR Guidance
2. Updated software feature *syngo* CTO Guidance
3. Updated software feature: Automatic model-based LA segmentation
4. Further Improvement of *syngo* DynaCT image quality
5. Proposed new product claims associated with device

The “*syngo* Application Software” may be installed either on Siemens released PC hardware or on Siemens X-ray systems also known as Siemens Angiography Systems. The combination of *syngo* Application Software and the Siemens released PC Hardware will be marketed as components of the *syngo* X Workplace.

The *syngo* Application Software is within the same classification regulation and the intended use and the general Indications for Use Statement for Siemens' Picture Archiving and Communications System.

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 is comparable to general Indications for Use for medical workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images and data on exchange media. The subject device has the same intended use, functionality, technology and is considered substantially equivalent to the commercially available Siemens' *syngo* Application Software.

All Software components of the subject device are the same as the one from the predicate device except for three updated software applications 1) *syngo* EVAR guidance and 2) *syngo* CTO Guidance and two further improved software

applications 3) Automatic model-based LA segmentation and 4) DynaCT: further improvement of image quality. The table below provides comparison of the Subject Device modification to the Predicate Device.

Subject and Predicate Device Comparison Information			
Property	Subject Device: syngo Application Software	Predicate Device: syngo Application Software (K153346)	Comparison Results
Updated Software-Applications	syngo EVAR Guidance: Automatic segmentation of the aorta and vessel tree Automatic identification and marking of anatomical structures	Manual segmentation of the aorta using punching functionality, manual marking of anatomical structures using syngo Toolbox functionality	Updated automated feature does not raise any new issues of safety or effectiveness. System Software Validation and testing was conducted
	syngo CTO Guidance: Automatic centreline extraction Warp view of CT data set	Manual marking of coronary segments using syngo Toolbox functionality VRT display of CT data set	Updated automated feature does not raise any new issues of safety or effectiveness. Validation and testing was conducted
Updated software feature:	Automatic model-based LA segmentation	One click LA segmentation	Updated automated feature does not raise any new issues of safety or effectiveness. Validation and testing was conducted.
Further modifications:	Improvements of DynaCT image quality: Reduce cupping and capping artifacts Improve visualization of intracranial soft-tissue	Standard Image quality: Visualization of intracranial soft-tissue	Improved image quality does not raise any new issues of safety or effectiveness. Validation and testing was conducted.

The Subject Device modifications do not alter its fundamental scientific technology from the 510(k) cleared predicate device Siemens' syngo Application Software.

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the syngo Application Software during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens claims conformance to the following performance standards: 14971; 60601-1-6; 62304; 62366; and NEMA PS3.

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 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. The syngo Application Software 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:

Verification and Validation testing was conducted on the following device software modifications: **1)** Updated software feature syngo EVAR Guidance **2)** Updated software feature syngo CTO Guidance **3)** Updated software feature: Automatic model-based LA segmentation as part of syngo LA segmentation **4)** Further Improvement of syngo DynaCT image quality All results are clinically accepted by either a board certified cardiologist or radiologist – all acceptance criteria have been met. 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 tests were conducted to test the functionality of the syngo Application Software. These tests have been performed to assess the overall system functionality of the subject device. Results of all conducted testing and clinical assessment were found acceptable and do not raise any new issues of safety or effectiveness.

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. 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 was cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that *syngo* Application Software 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.