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

March 4, 2016

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

Re: K153346
Trade/Device Name: syngo Application Software VD11
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2016
Received: February 8, 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,

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)*
K153346

Device Name
syngo Application Software VD11

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 VD11 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.

Section 7
510(k) Summary

The 510(k) Summary is provided on the next page and is suitable for publication on the FDA website.

510(k) Summary: *syngo* Application Software VD11

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

Date Prepared: March 2, 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 VD11
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* X Workplace
510(k) Clearance	K143319
Clearance Date	February 24, 2015
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 VD11 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 VD11 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* X Workplace (K143319).

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance for the Subject Device (*syngo* Application Software version VD11). The Subject Device is a modified version of the previously cleared *syngo* X Workplace software version VD10 cleared under Premarket Notification K143319 on February 24, 2015.

The following modifications are made to the cleared *syngo* X Workplace software version VD10 which created the Subject Device:

1. Updated Indications for Use Statement ***(Modification Affects: Labeling)***

2. VD10 Software renamed to VD11 (VD10 software features of the predicate device remain the same). The “syngo Application Software” VD11 consists of features cleared as SW Version VD10 in K143319. VD11 is provided as software only on a CD/DVD. ***(Modification Affects: Labeling).***

3. Provided update 510(k) information (see table below). The following minor modifications were made to the predicate device and are considered update 510(k) information for this submission.

.

Update Predicate Device Modifications Information	
1.	*syngo* X Workplace - new PC Hardware M720
2.	*syngo*.Interventional - VA30
3.	*syngo*.Interventional - VB10

The *syngo* Application Software VD11 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 VD11 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 VD11 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* X workplace. The Indications for Use Statement is slightly altered from the predicate, but the intended use of the device remains the same.

All Software components of the subject device are the same as the one from the predicate device.

The Subject Device modifications do not alter its fundamental scientific technology from the 510(k) cleared predicate device Siemens' *syngo* X Workplace. See table below:

Technological Characteristic	**Subject Device: "*syngo* Application Software" SW VD11 on CD/DVD Only**	**Predicate Device: *syngo* X Workplace SW VD10 K143319**	**Comparison Results**
Unchanged SW Applications	*syngo* Dyna3D	*syngo* Dyna3D	Same
	syngo DynaCT	*syngo* DynaCT	Same
	syngo DynaCT Cardiac	*syngo* DynaCT Cardiac	Same
	syngo DynaPBV Neuro	*syngo* DynaPBV Neuro	Same
	syngo DynaPBV Body	*syngo* DynaPBV Body	Same
	syngo DynaCT Large Volume	*syngo* DynaCT Large Volume	Same
	syngo DynaCT 360	*syngo* DynaCT 360	Same
	syngo Dyna3D HighSpeed	*syngo* Dyna3D HighSpeed	Same
	syngo DynaCT Micro	*syngo* DynaCT Micro	Same
	syngo Needle Guidance	*syngo* Needle Guidance	Same
	syngo Electrophysiology Guidance	*syngo* Electrophysiology Guidance	Same
	syngo Aortic Valve Guidance	*syngo* Aortic Valve Guidance	Same
	syngo 3D Stenosis measurement	*syngo* 3D Stenosis measurement	Same
	syngo Neuro Aneurysm Analysis *syngo* Neuro Virtual Stent	*syngo* Neuro Aneurysm Analysis *syngo* Neuro Virtual Stent	Same
	syngo 3D/3D Fusion	*syngo* 3D/3D Fusion	Same
	syngo Toolbox	*syngo* Toolbox	Same
	syngo 3D Roadmap	*syngo* 3D Roadmap	Same
	syngo Dual Volume	*syngo* Dual Volume	Same

	syngo Angio (DSA)	*syngo* Angio (DSA)	Same
	syngo Composing (AX/MR) -*syngo* AngioLeg Composing -*syngo* Spine Composing -*syngo* OrthoLeg Composing -*syngo* Ortho Measurement -*syngo* Ortho Report	*syngo* Composing (AX/MR) -*syngo* AngioLeg Composing -*syngo* Spine Composing -*syngo* OrthoLeg Composing -*syngo* Ortho Measurement -*syngo* Ortho Report	Same
	syngo iFlow	*syngo* iFlow	Same
	syngo QVA (Quantitative Vascular Analysis)	*syngo* QVA (Quantitative Vascular Analysis)	Same
	syngo QCA (Quantitative Coronary Analysis)	*syngo* QCA (Quantitative Coronary Analysis)	Same
	syngo LVA and *syngo* LVA Biplane (Left Ventricular Analysis)	*syngo* LVA and *syngo* LVA Biplane (Left Ventricular Analysis)	Same
	syngo IZ3D (3D-Quant)	*syngo* IZ3D (3D-Quant)	Same
	syngo 4D viewer: -Quick Zoom -*syngo* Dyna4D -3D Wizard -*syngo* 2/D/3D Fusion -*syngo* DynaCT SMART -Dedicated Graphical User Interface	*syngo* 4D viewer: -Quick Zoom -*syngo* Dyna4D -3D Wizard -*syngo* 2/D/3D Fusion -*syngo* DynaCT SMART -Dedicated Graphical User Interface	Same
syngo Standard Services	Patient Browser Viewer (CT, MR, X-ray, NM, PET, US), DICOM SR Viewer, 2D image display Filming and Hardcopy Archiving and Networking -DICOM Storage -DICOM Storage Commitment -DICOM Query & Retrieve -DICOM Media Storage -DICOM Print -Archiving (CD-R, DVD, film) -Compression (JPEG, lossy and lossless - 8 or 12 bit) -Communication (TCP/IP standard communication protocol)	Patient Browser Viewer (CT, MR, X-ray, NM, PET, US), DICOM SR Viewer, 2D image display Filming and Hardcopy Archiving and Networking -DICOM Storage -DICOM Storage Commitment -DICOM Query & Retrieve -DICOM Media Storage -DICOM Print -Archiving (CD-R, DVD, film) -Compression (JPEG, lossy and lossless - 8 or 12 bit) -Communication (TCP/IP standard communication protocol)	Same
syngo Extended Services	Security Package 3D Basic: Multiplanar Reconstruction (MPR) Surface Shaded Display (SSD) Maximum/Minimum Intensity Projection (MIP) 3D Volume Rendering Technique (VRT) Editor package Fly Through Image Fusion: CT, MR, NM, PET	Security Package 3D Basic: Multiplanar Reconstruction (MPR) Surface Shaded Display (SSD) Maximum/Minimum Intensity Projection (MIP) 3D Volume Rendering Technique (VRT) Editor package Fly Through Image Fusion: CT, MR, NM, PET	Same

OEM software	Microsoft™ Office 2010™ Internet Explorer™ TrendMicro Antivirus Program Version 10.6 at a minimum CamTasia Studio Version 1.1.1 (or higher)	Microsoft™ Office 2010™ Internet Explorer™ TrendMicro Antivirus Program Version 5.02 at a minimum CamTasia Studio Versio96 n 1.1.1 (or higher)	Same
Integrated Quantification	Quant including QCA 3D K063344	Quant including QCA 3D K063344	Same
Operating System	Windows 7	Windows 7	Same
Image Archiving	CD-R, DVD, Blue ray, film	CD-R, DVD, Blue ray, film	Same

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the *syngo* Application Software VD11 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 VD11 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 including was found acceptable to support the claims of substantial equivalence.

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:

Performance tests were conducted to test the functionality of the *syngo* Application Software VD11. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing and clinical

images 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. Similar non-clinical test results demonstrate that *syngo* Application Software VD11 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.