

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

<u>http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</u> 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,

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)

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

provides image guided solutions in the operating room, for image guided surgery, by Image Fusion and by navigation processing, and reporting workstation. It can also be configured within a network to send and receive DICOM data interventional oncology, interventional radiology, and interventional neuroradiology. systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for Furthermore, the syngo Application Software can be deployed on systems of the Siemens Angiography system family. It The syngo Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-

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

available post-processing techniques and OEM options. which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially The syngo Application Software VD11 can be configured with a variety of syngo or Windows-based software options,

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

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Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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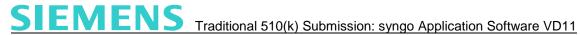
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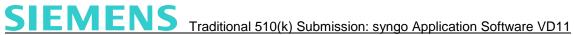
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Section 7 510(k) Summary

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:**

syngo Application Software VD11 **Trade Name:**

Classification Name: Picture Archiving and Communications system

Classification Panel: Radiology

21 CFR §892. 2050 Classification Regulation:

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

Class II **Device Class: 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 quided solutions interventional cardiology systems, image in 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.

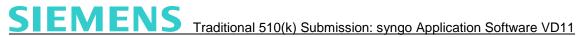
7. Summary of Technological Characteristics of the Subject Device as **Compared with the Predicate Device:**

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: s <i>yngo</i> X Workplace SW VD10 K143319	Comparison Results
Unchanged	syngo Dyna3D	syngo Dyna3D	Same
SW	syngo DynaCT	syngo DynaCT	Same
Applications	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 Composing (AX/MR)	Same
	-syngo AngioLeg Composing	-syngo AngioLeg Composing	Carrio
	-syngo Spine Composing	-syngo Spine Composing	
	-syngo OrthoLeg Composing	-syngo OrthoLeg Composing	
	-syngo Ortho Measurement	-syngo Ortho Measurement	
	-syngo Ortho Report	-syngo Ortho Report	
	syngo iFlow	syngo iFlow	Same
	syngo QVA (Quantitative	syngo QVA (Quantitative	Same
	Vascular Analysis)	Vascular Analysis)	Game
	syngo QCA (Quantitative	syngo QCA (Quantitative	Same
	Coronary Analysis)	Coronary Analysis)	Game
	syngo LVA and syngo LVA	syngo LVA and syngo LVA	Same
	Biplane (Left Ventricular	Biplane (Left Ventricular	Game
	Analysis)	Analysis)	
	syngo IZ3D (3D-Quant)	syngo IZ3D (3D-Quant)	Same
	syngo 4D viewer:	syngo 4D viewer:	Same
	-Quick Zoom	-Quick Zoom	Camo
	-syngo Dyna4D	-syngo Dyna4D	
	-3D Wizard	-3D Wizard	
	-syngo 2/D/3D Fusion	-syngo 2/D/3D Fusion	
	-syngo DynaCT SMART	-syngo DynaCT SMART	
	-Dedicated Graphical User	-Dedicated Graphical User	
	Interface	Interface	
syngo	Patient Browser	Patient Browser	Same
Standard	Viewer (CT, MR, X-ray, NM,	Viewer (CT, MR, X-ray, NM,	
Services	PET, US), DICOM SR Viewer,	PET, US), DICOM SR Viewer,	
	2D image display	2D image display	
	Filming and Hardcopy	Filming and Hardcopy	
	Archiving and Networking	Archiving and Networking	
	-DICOM Storage	-DICOM Storage	
	-DICOM Storage Commitment	-DICOM Storage	
	-DICOM Query & Retrieve	Commitment	
	-DICOM Media Storage	-DICOM Query & Retrieve	
	-DICOM Print	-DICOM Media Storage	
	-Archiving (CD-R, DVD, film)	-DICOM Print	
	-Compression (JPEG, lossy	-Archiving (CD-R, DVD, film)	
	and lossless - 8 or 12 bit)	-Compression (JPEG, lossy	
	-Communication (TCP/IP	and lossless - 8 or 12 bit)	
	standard communication	-Communication (TCP/IP	
	protocol)	standard communication	
		protocol)	
syngo	Security Package	Security Package	Same
Extended	3D Basic:	3D Basic:	
Services	Multiplanar Reconstruction	Multiplanar Reconstruction	
	(MPR)	(MPR)	
	Surface Shaded Display (SSD)	Surface Shaded Display (SSD)	
	Maximum/Minimum Intensity	Maximum/Minimum Intensity	
	Projection (MIP)	Projection (MIP)	
	3D Volume Rendering Technique	3D Volume Rendering	
	(VRT)	Technique (VRT)	
	Editor package	Editor package	
	Fly Through	Fly Through	
	Image Fusion: CT, MR, NM, PET	Image Fusion: CT, MR, NM,	
		PET	



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. Nonclinical 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 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.