K123920

JAN 18 2013

510(k) Summary

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

I. General Information

Establishment:

- Address: Siemens AG, Medical Solutions
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  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Sabine Schroedel
  Regulatory Affairs Manager
  Telephone: +49 (9131) 84-8285
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Device Name and Classification:

- Trade Name: *syngo*.via
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination

Device Description and Intended Use:
This premarket notification covers Siemens' enhanced PACS system *syngo.*via.
*syngo.*via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo.*via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.
The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

The system is a software only medical device. It defines minimum requirements to the hardware it runs on. The hardware itself is not seen as a medical device and not in the scope of this 510(k) submission.

It supports the physician in diagnosis and treatment planning. *syngo.*via also supports storage of Structured DICOM Reports.

In a comprehensive imaging suite *syngo.*via integrates Radiology Information Systems (RIS) to enable customer specific workflows.

The predicate device, *syngo.*via allows for the use of a variety of advanced applications (clinical applications) These applications are medical devices on their own rights and filed separately. They are not part of this 510(k) submission and not part of the *syngo.*via medical device. *syngo.*via has a universal component called generic reader application which is part of this medical device and it allows no newly introduced imaging and post processing algorithms compared to the above mentioned predicate devices.

syngo.via is based on Windows. Due to special customer requirements and the clinical focus *syngo.*via can be configured in the same way as the predicate device with different combinations of *syngo*- or Windows - based software options and clinical applications which are intended to assist the physician in diagnosis and/or treatment planning. This includes commercially available post-processing software packages.

*syngo.*via Data Management

... ensures all authorized personnel fast and continuous access to radiological data. It's main functionality ranges from availability of images with regard to data security, open interfaces, storage media and central system administration, to provide a flexible storage hierarchy.

Integration:

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the *syngo* product family a consistent workflow – from patient registration to requirement scheduling to a personal work list and supports therefore reporting, documentation or administrative tasks.

Technological Characteristics:

syngo.via is a "software only"-system, which will be delivered on CD-ROM / DVD to be installed on common IT hardware. This hardware has to fulfil the defined requirements.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on Windows XP, Windows Vista and Windows 7. Any hardware platform, which complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported.

The herewith described *syngo*.via supports DICOM formatted images and objects.

The *syngo*.via will be marketed as a software only solution for the end-user (with recommended hardware requirements). Any special needs such as integration in a specific environment and updates / upgrades will be covered by individual service contract and fulfilled by special trained service technicians.
syngo.via will be used for viewing, manipulation, communication, and storage of medical images. The predicate device *syngo*.via is also capable of viewing, manipulation, communication, and storage of medical images.

The difference between the *syngo*.via and the predicate device *syngo*.via are to give the subject device greater capabilities than the predicate device. *syngo*.via has similar technological characteristics as the predicate device and is similar to the functionalities of the predicate device.

Predicate Device Comparison Table

Functionality	Principal Device *syngo*.via	Predicate Device *syngo*.via VA20A	Predicate Device SOMATOM Definition Edge CT System	Predicate Device *syngo*. CT Vascular Analysis	Predicate Device *Software syngo MR D13A for MAGNETRON systems.*	Predicate Device *syngo* TrueD
FDA Clearance		K123375	K120579	K112020	K121434	K101749
Manufacturer	Siemens AG Medical Solutions	Siemens AG Medical Solutions	Siemens AG Medical Solutions	Siemens AG Medical Solutions	Siemens AG Medical Solutions	Siemens AG Medical Solutions
Intended Use	*syngo*.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options. *syngo*.via supports	syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options. syngo. via supports	The Siemens SOMATOM Definition Edge (Project P46F) systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.(*spiral planes: the axial	*syngo*.CT Vascular Analysis is an image analysis software package for evaluating enhancedCT images. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP	The MAGNETOM systems described above are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or	*syngo* TrueD is a medical diagnostic application for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR.

	interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not approved in the U.S. for the displaying of digital mammography images for diagnosis.	interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The system is not approved in the U.S. for the displaying of digital mammography images for diagnosis.	planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)	thin/thick, volume rendering technique (VRT), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such	extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis. The MAGNETOM systems described above may also be used for imaging during interventional procedures when performed with MR compatible devices	The images can be viewed in a number of output formats including MIP and volume rendering. *syngo* TrueD enables visualization of information that would otherwise have to be visually compared disjointedly. *syngo* TrueD provides analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. *syngo* TrueD is designed to support the oncological workflow by helping the user to confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation

				lesion. These visualization/processing/evaluation tools allow for characterization of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue.	such as in-room display and MR-safe biopsy needles	of any such lesions. The application allows to store and export volume of interest (VOI) structures in DICOM RT format for use in radiation therapy planning systems. *syngo* TrueD allows visualization and analysis of respiratory gated studies to support accurate delineation of the target or treat-treat-ment volume over a defined phase of the respiratory cycle and thus provide information for radiation therapy planning.
Image communication	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image	Standard network protocols like TCP/IP and standard communication protocol DICOM.	Not Applicable – not a stand-alone medical device.	Standard network protocols like TCP/IP and standard communication protocol DICOM.	Standard network protocols like TCP/IP and standard communication protocol DICOM.

	transfer protocol for use inside syngo®.via.	transfer protocol for use inside syngo®.via.				
Image data compression	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate. Receive and decompress of JPEG2000 compressed images.	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate. Receive and decompress of JPEG2000 compressed images.	None	None	None	None
Imaging Algorithms	MPR; MIP; MinIP; VRT; SSD; Digitally Reconstructed Radiograph; Editor functionality / ClipBox / ClipPlane; Registration; Region Growing; Quantitative measurements such as distance; angle.	MPR; MIP; MinIP; VRT; SSD; Digitally Reconstructed Radiograph; Editor functionality / ClipBox / ClipPlane; Registration; Region Growing; Quantitative measurements such as distance; angle.	N/A	N/A	N/A	
Hardware/OS	Client: PC with Windows XP, Windows Vista, Windows 7	Client: PC with Windows XP, Windows Vista, Windows 7	PC with Windows XP Professional, Celsius Hardware	Not Applicable – not a stand-alone medical device.	Minimum Requirements - Intel Pentium IV Processor, 2.00 GHz, MS Win-	PC with Windows XP Professional, Celsius Hardware

	Server Windows Server 2008 R2 (HW is not understood as part of the medical device, but needs to comply to the minimum requirements as specified by syngo.via)	Server Windows Server 2008 R2 (HW is not understood as part of the medical device, but needs to comply to the minimum requirements as specified by syngo.via)			dows XP SP1 or later	
Major Safety Characteristics	subject device is a post-processing software package with no implemented capability to control the connected modalities; support of quality assurance methods such as SMPTE; HIPAA; major software self tests / checks.	subject device is a post-processing software package with no implemented capability to control the connected modalities; support of quality assurance methods such as SMPTE; HIPAA; major software self tests / checks.	Software package attached to Modality Scanner (CT)	subject device is a post-processing software package with no implemented capability to control the connected modalities; support of quality assurance methods such as SMPTE; HIPAA; major software self tests / checks.	Software package attached to Modality Scanner (MR)	subject device is a post-processing software package with no implemented capability to control the connected modalities; support of quality assurance methods such as SMPTE; HIPAA; major software self tests / checks.
Automatic Spine Labeling						
Anatomy Labeling	Anatomy labels are automatically suggested, with manual override possible.	Not applicable	Anatomy labels are automatically suggested, with manual override possible.	Anatomy labels are automatically suggested, with manual override possible.	Anatomy labels are automatically suggested, with manual override possible.	N/A
Anatomy Labelled	Vertebra bodies	Not applicable	Vertebra bodies and discs	Coronary vessels.	Vertebra bodies and discs	N/A
Labeling Workflow	Automatically suggested labels are	Not applicable	Automatically suggested labels are	Automatically suggested labels are	Automatically suggested labels are	N/A

	displayed by launching the work-flow function. Editing of labels is provided to override the automatically suggested labels.		displayed by launching the work-flow function. Editing of labels is provided to override the automatically suggested labels.	displayed by launching the work-flow function. Editing of labels is provided to override the automatically suggested labels.	displayed by launching the work-flow function. Editing of labels is provided to override the automatically suggested labels.	
Labeling Confirmation	A caution message is overlaid on screen informing the user that they have to confirm the accuracy of the spine labels. Once the labels have been checked for accuracy, the caution message can be dismissed via a GUI button.	Not applicable	A reconstruction job icon indicates to the user that confirmation is required before performing the reconstruction and finalizing the labeling of vertebrae. Once the labels have been checked for accuracy, the caution message can be dismissed via a GUI button.	N/A	A verification step is provided where the user must confirm the accuracy labelling before proceeding. Once the labels have been checked for accuracy,using a GUI button , the user can manually start the reconstruction.	N/A
Labeling Editing	Supports manual and semi-automatic editing of labels, through insertion and deletion of la-	Not applicable	Supports manual and semi-automatic editing of labels, insertion and dele-	Supports manual editing of labels, including insertion and deletion of la-	Supports manual editing of labels, including insertion and deletion of labels.	N/A

	bels. Menu of spine labels names provided.		tion of labels. Menu of spine labels names provided.	bels. Menu of vessel labels names provided.	Menu of spine labels names provided.	
Modalities Supported	Cross-sectional imaging (CT, MR)	Not applicable	Cross-sectional imaging (CT)	Cross-sectional imaging (CT)	Cross-sectional imaging (MR)	N/A
Anatomical Registration						
Automated Anatomical Registration	Landmark-based alignment	Not applicable	N/A	N/A	N/A	Landmark-based alignment
Time-points	Across multiple time-points	Not applicable	N/A	N/A	N/A	Across multiple time-points
Modalities	Cross-sectional imaging (CT, MR)	Not applicable	N/A	N/A	N/A	Cross-sectional imaging (CT)
User Verification	Registration verification by user	Not applicable	N/A	N/A	N/A	Registration verification by user
Adjustments	Manual registration adjustments made	Not applicable	N/A	N/A	N/A	Manual registration adjustments made through visual tools

	through visual tools					

Summary of Non-Clinical Tests:

Summary of Non-Clinical Tests:

The software verification and validation (Unit Test Level, Integration Test Level and System Test Level) was performed for all newly developend components and the complete system according to the following standards:

- DICOM Standard [2011]
- ISO/IEC 15444-1:2005+TC 1:2007
- ISO/IEC 10918-1:1994 + TC 1:2005
- HL7 [2006]
- IEC 62304:2006
- IEC 62366:2007
- ISO 14971:2007
- IEC 60601-1-4:2000

- **General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practice and standards.

syngo.via conforms to the applicable FDA recognized and international IEC, ISO, and NEMA standards with regards to performance and safety as recommended by the respective FDA Guidance Document.

- **Substantial Equivalence:**

The *syngo*.via extended functionalities addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Manu-facturer	*Predicate Device Name*	*FDA Clearance Number*
Siemens	*syngo*.via	K123375
Siemens	SOMATOM Definition Edge CT System	K120579
Siemens	*syngo*.CT Vascular Analysis	K112020
Siemens	Software *syngo* MR D13A for MAGNETOM systems Aera/Skyra/Avanto/Verio	K121434
Siemens	*syngo* TrueD	K101749

The added capabilities to *syngo*.via described in this 510(k) has similar functionalities that can be found in the devices listed above

In summary, Siemens is of the opinion that *syngo*.via does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 18, 2013

Siemens AG Healthcare SY
% Mr. Norbert Stuiber
Responsible Third Party Official
TUV America Inc.
1775 Old Highway 8 NW
NEW BRIGHTON MN 55112

Re: K123920
Trade/Device Name: syngo®:via
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 14, 2012
Received: December 20, 2012

Dear Mr. Stuiber:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):_____
Device Name: *syngo*®.via

Indications For Use:

syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images.
It can be used as a stand-alone device or together with a variety of cleared and unmodified *syngo* based software options.

syngo.via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Prescription Use X AND / OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K123920

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