K 130998

JAN - 3 2014

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 Henkestrasse 127 D-91052 Erlangen Germany
• Registration Number:	3002808157
• Contact Person:	Joerg Teiche Telephone: +49 (9131) 84-4687 Telefax: +49 (9131) 84-8691

Device Name and Classification:

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

Date of submission: April 2013

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

Indications for Use:

syngo.via WebViewer is a software-only device indicated for reviewing medical images from *syngo*.via. It supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments (supported Image types: CT, MR, CR, DR, DX, PET). It is not intended for storage or distribution of medical images.

syngo.via WebViewer is an option for the *syngo*.via system and cannot be run without it. It is client server architecture and the client is intended to run on web clients which are connected to the healthcare institution IT infrastructure where the customer will insure HIPAA compliance. The communication of *syngo*.via WebViewer with connected medical IT systems will be done via standard interfaces such as but not limited to DICOM.

The system is not intended for the display of digital mammography images for diagnosis.

Device Description:

The *syngo*.via WebViewer is a software-based Picture Archiving and Communications System (PACS) used with the *syngo*.via system. The *syngo*.via WebViewer provides secure access to rendered medical image data and basic image manipulation through web browsers and mobile devices within the reach of the hospital network.

It extends the syngo.via WebViewer software application previous cleared under K111079. New image types supported are PET and X-Ray images. It also provides functionality for displaying images via a mobile application on an iPad.

syngo.via WebViewer 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.

Integration:

The Workflow Management enables by integration of any HL7- / DICOM-compatible RIS (IHE Year 5) to the *syngo* product family consistent workflow within the healthcare organization.

Technological Characteristics:

syngo.via WebViewer server part 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 Software will be installed by Siemens service engineers only.

The backend communication and storage solution is based on Windows 2008 operating system. The client machines are based on standard computer (Mac / Windows PC / Linux PC). The web

and mobile client application runs in a standard web browser - such as but not limited to Internet Explorer, Firefox, Safari – please refer to the specification for the complete list of supported web browsers.

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 WebViewer supports DICOM formatted images (CT, MR, CR, DR, DX, PET) and objects (SC, pdf).

The *syngo*.via WebViewer will be marketed as a software only solution for the end-user (with recommended hardware requirements). The server part will be installed by trained service engineers only. 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.

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 developed 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 labelling contains instructions for use and any necessary cautions and warnings, 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.

Substantial Equivalence:

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

Manufacturer	*Predicate Device Name*	*FDA Clearance Number*
Siemens	*syngo*.via WebViewer	K111079

The *syngo*.via WebViewer described in this 510(k) has similar intended use and similar technical characteristics as the device listed below in regard to the specific functionalities.

Device Comparison Table between new device and predicate device:

Functionality	*syngo*.via WebViewer VA11	*syngo*.via WebViewer VA10A
Manufacturer	identical	identical
Intended use	*syngo*.via WebViewer is a software-only device indicated for reviewing medical images from *syngo*.via. It supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments (supported Image types: CT, MR, CR, DR, DX, PET). It is not intended for storage or distribution of medical images. *syngo*.via WebViewer is an option for the *syngo*.via system and cannot be run without it. It is client server architecture and the client is intended to run on web clients which are connected to the healthcare institution IT infrastructure where the customer will insure HIPAA compliance. The communication of *syngo*.via WebViewer with connected medical IT systems will be done via standard interfaces such as but not limited to DICOM. The system is not intended for the display of digital mammography images for diagnosis.	*syngo*.via WebViewer is intended to be a software-only solution for reviewing medical images from *syngo*.via. The system cannot be used as stand-alone device. It is intended to be an option for *syngo*.via system only. *syngo*.via WebViewer is not intended for storage or distribution of medical images from one medical device to another. *syngo*.via WebViewer is a client server architecture and the client is intended to run on web clients which are connected to the healthcare institution IT infrastructure where the customer has to ensure HIPAA compliance. *syngo*.via WebViewer supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments. The communication of *syngo*.via WebViewer with connected medical IT systems will be done via standard interfaces such as but not limited to DICOM. The system is not intended for the

Functionality	*syngo*.via WebViewer VA11	*syngo*.via WebViewer VA10A
		displaying of digital mammography images for diagnosis in the U.S
Image communication	identical	identical
Image Processing and Evaluation	identical	identical
Supported Image Types	MR, CT, SC, PDF, PET, CR, DX	MR, CT, SC, PDF
Image data compression	identical	identical
User administration	UI is *syngo*®-based web client and mobile client	UI is *syngo*®-based web client
User Interface	identical	identical
Hardware	Client: PC with Windows System or MAC with Mac iOS Server: Windows Server 2008 SP1 iPad (with iOS 5.0 or 5.1)	Client: PC with Windows System, MAC with Mac OS Server: Windows Server 2008
Imaging Algorithms	MPR, MIP, VRT, PET/CT, SUV	MPR, MIP, VRT
Quantitative Algorithms	identical	identical

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

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

January 3, 2014

Siemens AG, Medical Solutions
% Ms. Sabine Schroedel
Regulatory Affairs Manager
Henkestrasse 127
Erlangen, Bavaria 91052
GERMANY

Re: K130998
Trade/Device Name: syngo.via WebViewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 19, 2013
Received: December 20, 2013

Dear Ms. Schroedel:

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.

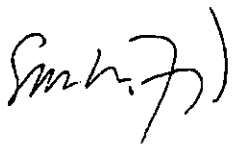
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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. 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,



for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130998

Device Name
syngo®.via WebViewer

Indications for Use *(Describe)*
syngo.via WebViewer is a software-only device indicated for reviewing medical images from syngo.via. It supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments (supported Image types: CT, MR, CR, DR, DX, PET). It is not intended for storage or distribution of medical images.

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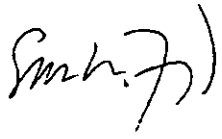
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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