



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Siemens AG
% Ms. Dawn Tibodeau
Third Party 510(k) Project Coordinator
TUV SUD America, Inc.
1775 Old Highway 8 NW
NEW BRIGHTON MN 55112-1891

April 24, 2015

Re: K150843
Trade/Device Name: syngo[®].via (version VB10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 26, 2015
Received: March 30, 2015

Dear Ms. Tibodeau:

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 black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the letters "FDA" in a bold, sans-serif font.

Robert Ochs, Ph.D.
Acting 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)

K150843

Device Name

syngo®.via (Version VB10A)

Indications for Use (Describe)

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.

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.

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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.

Date prepared: March 18, 2015

1. Submitter:

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3. 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

4. Legally Marketed Predicate Device:

Trade Name: *syngo.via*
510(k) Clearance: K123920
Clearance Date: January 18, 2013
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:

Siemens AG intends to market the Picture Archiving and Communications System, *syngo.via*, software version VB10A. This 510(k) submission describes several modifications to the previously cleared predicate device, *syngo.via*, software version VA20A.

syngo.via is a software only medical device, which is delivered on DVD to be installed on common IT hardware. This hardware has to fulfil the defined requirements. Any hardware platform that complies to the specified minimum hardware and software requirements and with successful installation verification and validation activities can be supported. The hardware itself is not seen as part of the medical device *syngo.via* and therefore not in the scope of this 510(k) submission.

syngo.via provides tools and features to cover the radiological tasks *reading images* and *reporting*. *syngo.via* supports DICOM formatted images and objects. *syngo.via* also supports storage of Structured DICOM Reports. In a comprehensive imaging suite, *syngo.via* interoperates with a Radiology Information System (RIS) to enable customer specific workflows.

syngo.via is based on a client-server architecture. The server processes and renders the data from the connected modalities. The server provides central services including image processing and temporary storage, and incorporates the local database. The client provides the user interface for interactive image viewing and processing and can be installed and started on each workplace that has a network connection to the server.

The server's backend communication and storage solution is based on Microsoft Windows server operating systems. The client machines are based on Microsoft Windows operating systems.

syngo.via supports various monitor setups and can be adapted to a range of image types by connecting different monitor types.

The subject device and the predicate device share the same fundamental scientific technology. This device description holds true for the subject device, *syngo.via*, software version VB10A; as well as the predicate device, *syngo.via*, software version VA20A.

6. 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 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.

7. Summary of Differences between the Subject Device and the Predicate Device:

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

	Subject device <i>syngo.via VB10A</i>	Predicate device <i>syngo.via VA20A</i>
Software architecture	Client-server architecture that is logically broken down to <i>syngo.via</i> subsystems. Subsystems are further broken down to <i>syngo</i> modules.	Client-server architecture that is logically broken down to <i>syngo.via</i> subsystems
Operating systems	Client: Microsoft Windows 7 SP1 or Microsoft Windows 8.1 Server: Microsoft Windows Server 2008 R2, or Microsoft Windows Server 2012 R2	Client: Microsoft Windows XP, Microsoft Windows Vista, or Microsoft Windows 7 Server: Microsoft Windows Server 2008 R2
Imaging algorithms	Volume Rendering Technique (VRT) with additional input parameters for edge and surface enhancement and control over rendering parameters Automatic Spine Labeling, also for ribs in CT thorax scans	Volume Rendering Technique (VRT) Automatic Spine Labeling
Software functionality	Graphical user interface with reduced color palette, clearer structure and text labels on icons. Online help system with improved search, indexing, filtering, library function, document collections, and user-generated content. Reporting with additional functionality to create one page reports, insert snapshot images, customize reports, and data export in various formats. Patient browser with simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results, image preview and flexible floating patient browser window. Correct and rearrange of data Added anatomical range presets, support for spine ranges, and annotations as graphical overlays.	Graphical user interface with a defined color palette and iconic buttons. Online help system with basic search functionality. Reporting with basic report templates and basic data export functionality. Patient browser with search functionality across a variety of data, results list showing study and procedure information. Correct and rearrange not available. Basic functionality to create a series (range) of images and export a range.

	<p>Suggested spine labels to be confirmed by user, and additional smart placement of labels, also in inter-vertebra regions, support of 2D images, support of multi-series studies, and added support for rib labels.</p> <p>Printing with additional options for rearranging images, adding annotations, full/customized image text, print size and orientation.</p> <p>Configurable settings for image text.</p> <p>Added textual and graphical annotations, improved placement of measurement text, and changed numbering of markers.</p>	<p>Suggested spine labels to be confirmed by user.</p> <p>Printing with image text on DICOM printer or paper printer.</p> <p>Show or hide image text.</p> <p>Marking a position on an image and textual annotations.</p>
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8. Non-clinical Performance Testing:

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

Siemens claims conformance to the following standards:

- NEMA PS3 Digital Imaging and Communications in Medicine (DICOM)
- ISO IEC 10918-1:1994 + Technical Corrigendum 1:2005 (JPEG)
- ISO IEC 15444-1:2005 + Technical Corrigendum 1:2007 (JPEG 2000)
- ISO 14971:2007
- ANSI/AAMI ES 60601-1, A 1, clauses 14.11 and 14.13
- IEC 62304:2006
- IEC 62366:2007, clauses 4, 5.1 through 5.9, 6 and 7
- ISO/HL7 21731:2006

Software 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 device *syngo.via* during product development.

The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing results support 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.

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. Contained in Section B of this submission are our cybersecurity considerations as they relate to the device *syngo.via*.

Summary:

Performance tests were conducted to test the functionality of the device *syngo.via*. These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

9. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device.

The results of the hazard analysis combined with the appropriate preventive measures taken indicate the device is of moderate level of concern, as per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

10. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. The comparison of technological characteristics, device hazards, non-clinical performance data, and software validation data demonstrates that the subject device performs comparably to and is as safe and effective as the predicate device that is currently marketed for the same intended use.

In summary, we are of the opinion that the subject device *syngo.via*, software version VB10A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.