Siemens Healthcare GmbH
% Alexander Schapovalov
Responsible Third Party Reviewer
TÜV SÜD America Inc.
1775 Old Highway 8
NEW BRIGHTON, MN 55112

September 7, 2018

Re: K182208
Trade/Device Name: syngo.via View&GO (Version VA10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 2, 2018
Received: August 15, 2018

Dear Alexander Schapovalov:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

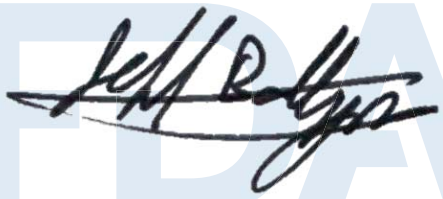
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182208

Device Name
syngo.via View&GO (Version VA10A)

Indications for Use *(Describe)*
syngo.via View&GO 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 View&GO 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 US.

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.

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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: July 18, 2018

1. **Submitter:**
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   Establishment Registration Number:
   3004977335

2. **Contact Person:**
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3. **Device Name and Classification:**

Trade Name:	*syngo*.via View&GO (Version VA10A)
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:	K150843
Clearance Date:	April 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 doesn't have any open design related recalls.

5. Device Description:

Siemens Healthcare GmbH intends to market the Picture Archiving and Communications System, *syngo*.via View&GO, software version VA10A. This 510(k) submission describes several modifications to the previously cleared predicate device, *syngo*.via, software version VB10A.

syngo.via View&GO is a software only medical device, which is delivered by download 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 View&GO and therefore not in the scope of this 510(k) submission.

syngo.via View&GO provides tools and features to cover the radiological tasks *preparation for reading*, *reading images* and *support for reporting*[14]. *syngo*.via View&GO supports DICOM formatted images and objects.

syngo.via View&GO is a standalone viewing and reading workplace. This is capable of rendering the data from the connected modalities for the post processing activities. *syngo*.via View&GO provides the user interface for interactive image viewing and processing with a limited short term storage which can be interfaced with any Long term storage (e.g. PACS) via DICOM.

syngo.via View&GO is based on Microsoft Windows operating systems.

syngo.via View&GO 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.

6. Indications For Use:

syngo.via View&GO 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 View&GO 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.

[14] Support for reporting is provided in the tool with the clipboard functionality so that the image with measurements and annotations can be copied to any 3rd party reporting tools.

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

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

	Subject device *syngo*.via View&GO VA10A	**Predicate device *syngo*.via VB10A**	**Comparison**
Intended use	*syngo*.via View&GO 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 View&GO 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.	*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.	Same
Software architecture	Standalone workplace system that is logically broken down to *syngo*.via View&GO subsystems *syngo* modules.	Client-server architecture that is logically broken down to *syngo*.via subsystems *syngo* modules.	syngo.via View&GO is a standalone workplace rather syngo.via is based on Client-Server architecture

Image communication	Standard network protocols like TCP/IP and standard communication protocol DICOM.	Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image transfer protocol for use inside syngo.via between the client and server.	There is no internal communication as the subject device is a standalone software system.
Imaging algorithms	- Multiplanar reconstruction (MPR) - Maximum and Minimum Intensity Projection (MIP/MinIP) - Volume Rendering Technique (VRT) with additional edge and surface enhancements and control over rendering parameters - Shaded Surface Display (SSD) - Digitally Reconstructed Radiograph - Editor functionality (e.g. ClipBox) - Registration - Anatomical registration - Region growing Automatic Spine Labeling, also for ribs in CT thorax scans [15] ("Rib labeling")	- Multiplanar reconstruction (MPR) - Maximum and Minimum Intensity Projection (MIP/MinIP) - Volume Rendering Technique (VRT) with additional edge and surface enhancements and control over rendering parameters - Shaded Surface Display (SSD) - Digitally Reconstructed Radiograph - Editor functionality (e.g. ClipBox) - Registration - Anatomical registration - Region growing Automatic Spine Labeling, also for ribs in CT thorax scans [16] ("Rib labeling")	Same
Quantitative algorithms	Distance and angle measurements	Distance and angle measurements	Same

[15] Rib Labeling as a functionality was already covered by a 510(k) clearance with device *SYNGO*, CT BONE READING, K123584.
[16] Rib Labeling as a functionality was already covered by a 510(k) clearance with device *SYNGO*, CT BONE READING, K123584.

Supported Image Generating Modalities	- CT Image (Computed Tomography) - MR Image (Magnetic Resonance) - NM Image (Nuclear Medicine) - XA Image (X-Ray Angiography) - US Image (Ultrasound) - DX Image (Digital Radiography) - DICOM secondary capture objects	- CT Image (Computed Tomography) - MR Image (Magnetic Resonance) - NM Image (Nuclear Medicine) - XA Image (X-Ray Angiography) - US Image (Ultrasound) - DX Image (Digital Radiography) - DICOM secondary capture objects	Same
Image data Compression	Receive & Store: Images are received and stored as received without any change in the compression format. Display: Images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression ratio. Export: To DICOM Node: Images are sent as per the DICOM negotiation. Uncompressed is preferred and lossy compression is not supported. To Exchangeable media: Images exported as stored in the local storage. Supported Compressions for export: lossless compression algorithms, JPEG, JPEG 2000 and RLE.	Receive & Store: Images are received and stored as received without any change in the compression format. Display: The images are displayed as received without any change in the compression. Lossy compression images are displayed with an indication to the user with the compression ratio. Export: To DICOM Node and Exchangeable media: Images are sent as per the DICOM negotiation and depending on Compression settings. Lossy compression is not supported. Supported Compressions for export: lossless compression algorithms, JPEG, JPEG 2000 and RLE.	*syngo*.via has the option to configure the Image compression type for export but syngo.via View&GO is not having the option to configure.

Operating systems	Workplace: Microsoft Windows 7 – 64 bit SP1 Microsoft Windows 10 – 64 bit	Client: Microsoft Windows XP, Microsoft Windows Vista, or Microsoft Windows 7 Server: Microsoft Windows Server 2008 R2	There is no separate server in syngo.via View&GO.
Software functionality	Graphical user interface with reduced color palette, clearer structure and text labels on icons. Online help system provided in terms of the electronic user documents delivered as part of the installation of the medical device. Reporting functionality is not included in the syngo.via View&GO however the support for creation of reports with any 3rd party tool by enabling clipboard functionality. Patient browser with simplified search functionality, clearer structure of search results, unlimited search results, periodic updates of search results. Range pre-sets are not supported. Suggested spine labels to be confirmed by user,	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. Supports anatomical range pre-sets, support for spine ranges, and annotations as graphical overlays. Suggested spine labels to be confirmed by user, and additional smart placement of labels, also in inter-vertebra regions, support of 2D images,	syngo.via View&GO is a simplified version of syngo.via without the following key functionalities which are present in syngo.via: • Worklist handling • Task flow • Reporting • Findings Navigator

	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. Basic printing with paper is supported. Configurable settings for image text. Added textual and graphical annotations, improved placement of measurement text, and changed numbering of markers.	support of multi-series studies, and added support for rib labels. Printing with additional options for rearranging images, adding annotations, full/customized image text, print size and orientation. Configurable settings for image text. Added textual and graphical annotations, improved placement of measurement text, and changed numbering of markers.	
Impact on Image Generating Devices	None. *syngo*.via View&GO is a pure post processing software and there is no influence on the image generating devices.	None *syngo*.via is a pure post processing software and no influence on the image generating devices.	NA as both the devices doesn't impact the Image generating devices.
CAD Functionalities	None. No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel.	None. No automated diagnostic interpretation capabilities like CAD are included. All image data are to be interpreted by trained personnel.	NA as both the devices doesn't support any CAD functionalities.
Software self-test / checks	Intimate the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating system compatibility check during Installation.	Indicates the user in case that data coming from an interface cannot be assigned to a task flow to assign it manually. In case of a data mismatch due to incorrect or	Additional checks are there in syngo.via as syngo.via has the additional function-

	Medical device validation supports the end user to qualify their system for the clinical use.	inconsistent use of DICOM rules the administrator can change the data transfer protocol and patient identification rules.	alities like workflow handling, task flow, reporting.
Cyber Security	- User access control - Audit trails - Documentation of system security information, Network traffic & Firewall control - Support of virus / malware protection.	- User access control - Audit trails - Documentation of system security information, Network traffic & Firewall control - Support of virus / malware protection. - System Hardening	*syngo*.via View&GO doesn't provide the extensive system hardening which is provided by *syngo*.via.
Hardware	Hardware is not understood as part of the medical device, but needs to comply with the minimum requirements as specified by *syngo*.via View&GO.	Hardware is not understood as part of the medical device, but needs to comply with the minimum requirements as specified by *syngo*.via.	Same

8. Non-clinical Performance Testing:

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

Siemens Healthcare GmbH claims conformance to the following standards:

- NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communication in Medicine (DICOM)
- ISO IEC 10918-1:1994 + Technical Corrigendum 1:2005 (JPEG)
- ISO/IEC 15444-1:2016 (JPEG 2000)
- ISO 14971:2007
- IEC 62304:2006-05+AMD1:2015-06
- IEC 82304:2016-10
- IEC 62366-1:2015-02
- IEEE 3333.2.1-2015

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 View&GO 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 Healthcare GmbH 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 View&GO.

Summary:
Performance tests were conducted to test the functionality of the device *syngo*.via View&GO. 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 View&GO, software version VA10A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.