Siemens Healthcare GmBH
Frederike Jakob
Regulatory Affairs Manager
Siemensstraße 1, Forchheim
Erlangen, Bavaria
Germany

October 14, 2022

Re: K221501
Trade/Device Name: syngo.via View&GO
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 14, 2022
Received: September 15, 2022

Dear Frederike Jakob:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221501

Device Name
syngo.via View&GO VA30A

Indications for Use *(Describe)*
syngo.via View&GO is indicated for image rendering and post-processing of DICOM images to support the interpretation in the field of radiology, nuclear medicine and cardiology.

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: June 29, 2022

1. **Submitter:**
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   3004977335

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3. **Device Name and Classification:**

Trade Name:	*syngo*.via View&GO (Version VA30A)
Classification Name:	Medical Image Management and Processing System (PACS)
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 View&GO (Version VA20A)
510(k) Clearance:	K201477
Clearance Date:	July 1, 2020
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 Healthcare GmbH intends to market the Medical Image Management and Processing System, *syngo*.via View&GO, software version VA30A. This 510(k) submission describes several modifications to the previously cleared predicate device, *syngo*.via View&GO, software version VA20A.

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 reporting. *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. This device description holds true for the subject device, *syngo*.via View&GO, software version VA30A, as well as the predicate device, *syngo*.via View&GO, software version VA20A.

6. Intended Purpose:

6.1 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.

The subject device and the predicate device share an identical intended use.

6.2 Indications for Use

syngo.via View&GO is indicated for image rendering and post-processing of DICOM images to support the interpretation in the field of radiology, nuclear medicine and cardiology.

The subject device and the predicate device share identical indications for use. The indications for use fall within the scope of the intended use.

6.3 Contraindications

The system is not indicated for mammography images for diagnosis in the U.S.
The application is not to be used as an archiving device for patients' image data.
The application is not to be used as a sole basis for clinical decisions but further evidence has to be taken into account.

The subject device and the predicate device share substantially identical contraindications.

6.4 Patient Target Population

syngo.via View&GO has neither limitations concerning the patient population (e.g. age, weight, health, condition) nor limitations concerning region of body or tissue type.

The patient target population is identical for the subject device and the predicate device.

7. Summary of Differences between the Subject Device and the Predicate Device:
The following table compares the functionality of *syngo*.via View&GO VA30A to the predicate device *syngo*.via View&GO VA20A:

	Subject device	**Predicate device**	**Comparison**	**Impact to Safety & Effectiveness**
Device name and version (K number)	***syngo*.via View&GO (Version VA30A)**	***syngo*.via View&GO Version VA20A** (K201477)	New product version	NA
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	Identical	NA
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 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.	Identical	NA
Software architecture	Standalone workplace system that is logically broken down to *syngo*.via View&GO subsystems. Subsystems are further broken down to *syngo* modules.	Standalone workplace system that is logically broken down to *syngo*.via View&GO subsystems. Subsystems are further broken down to *syngo* modules.	Identical	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Image communication	Standard network protocols like TCP/IP and standard communication protocol DICOM.	Standard network protocols like TCP/IP and standard communication protocol DICOM.	Identical	NA
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 [1] - Reprocessing X-ray projection images into 3D image and Topograms [15] - FASTAlign	- 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 [2] ("Rib labeling") - Reprocessing X-ray projection images into 3D image and Topograms [16]	Similar: Algorithms underwent bug-fixing and minor improvements . No re-training or change in algorithm models was performed.	The changes between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures were taken for the safety and effectiveness of the subject device
Quantitative algorithms	Distance, angle & angle-on-stack, VOI and ROI measurements	Distance, angle, VOI and ROI measurements	Angle-Tool was extended with Angle-	The changes between the predicate device and the subject

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

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
			on-Stack functionality	device doesn't impact the safety and effectiveness of the subject device as the necessary measures were taken for the safety and effectiveness of the subject device
Supported Image Generating Modalities	The following Image types are supported by syngo.via View&GO: - 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	The following Image types are supported by syngo.via View&GO: - 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	Identical	NA
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:	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:	Identical	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	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.	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.		
Operating system	Workplace: Microsoft Windows 10 – 64 bit or higher Microsoft Windows 7 – 64 bit SP1 (for update only)	Workplace: Microsoft Windows 10 – 64 bit or higher Microsoft Windows 7 – 64 bit SP1 (for update only)	Identical	NA
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 View&GO is a pure post processing software and there is no influence on the image generating devices	NA as both the devices do not impact the Image generating devices.	NA
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 don't support any CAD functionalities .	NA
Software self-test / checks	Alert the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating system compatibility check during Installation.	Alert the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating system compatibility check during Installation.	Identical	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	Display Compatibility Check supports the end user to qualify the system for proper diagnostic use.	Display Compatibility Check supports the end user to qualify the system for proper diagnostic use.		
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.	Identical	NA
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* View&GO.	Identical	NA
Software Functionalities				
Graphical User Interface	Yes, with reduced color palette, clearer structure and text labels on icons.	Yes, with reduced color palette, clearer structure and text labels on icons	Similar – The changes are limited to the common look and feel based on Siemens Healthineers User Interface Style Guide.	The changes between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures were taken for the safety and effectiveness of the subject device.
Patient Browser	Yes, with simplified search functionality, clearer structure of search results, image preview, unlimited search results, periodic updates of search results.	Yes, with simplified search functionality, clearer structure of search results, image preview, unlimited search results, periodic updates of search results.	Identical	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Series navigator	The Series Navigator lists all currently loaded data within a workflow.	Yes, the Series Navigator lists all currently loaded data within a workflow.	Identical	NA
Findings / Reporting	No, reporting support is provided to create reports using any 3rd party reporting tool. Hence the findings also cannot be navigated.	No, reporting support is provided to create reports using any 3rd party reporting tool. Hence the findings also cannot be navigated.	Identical	NA
Import and export of data	Import of DICOM data from network nodes or external media, and of DICOM-compliant or non DICOM-compliant data from external media and Windows file system. Export to USB, Windows file system, or other DICOM nodes.	Import of DICOM data from network nodes or external media, and of DICOM-compliant or non DICOM-compliant data from external media and Windows file system. Export to USB, Windows file system, or other DICOM nodes.	Identical	NA
Archiving data	Data can be sent to an archive if *syngo.*via View&GO is connected to a PACS or corresponding DICOM node.	Data can be sent to an archive if *syngo.*via View&GO is connected to a PACS or corresponding DICOM node.	Identical	NA
Ranges	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are supported. Additionally, Anatomical Range presets [3] can be created.	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are supported. Additionally, Anatomical Range presets [4] can be created.	Spine Ranges and Range presets are also supported for MR images in the subject device.	This difference between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures were taken for the safety and

[3] Range Presets as a functionality was already covered by a 510(k) clearance with device syngo.via (version VB40A), K191040
[4] Range Presets as a functionality was already covered by a 510(k) clearance with device syngo.via (version VB40A), K191040

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
				effectiveness of the subject device.
Spine/Rib labeling	Yes, with suggested spine labels to be confirmed by the 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.	Yes, with suggested spine labels to be confirmed by the 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.	The Spine / Rib labeling functionality can be invoked directly from Corner Menu instead of invoking it via Range tool to facilitate direct access for the user. The underlying algorithm has not changed beyond bug fixing.	The changes between the predicate device and the subject device doesn't impact the safety and effectiveness of the subject device as the necessary measures were taken for the safety and effectiveness of the subject device
Communication	Yes, Interface with DICOM is supported.	Yes, Interface with DICOM is supported.	Identical	NA
Printing	Yes, both paper and DICOM printing supported.	Yes, both paper and DICOM printing supported.	Identical	N/A
Online help system	Yes, with reduced color palette, clearer structure and text labels on icons.	Yes, with reduced color palette, clearer structure and text labels on icons.	Identical	NA
Markers and annotations	Yes, - with support for marking a position on an image and textual annotations.	Yes, - with support for marking a position on an image and textual annotations.	Identical	NA

Table 1: Substantial equivalency information

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 (2016a) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO/IEC 10918-1 First edition 1994-02-15 + Technical Corrigendum 1 (2005) (JPEG)
- ISO/IEC 15444-1:2016 (JPEG2000)
- ISO 14971 Second edition 2007-03-01
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 82304-1 Edition 1.0 2016-10
- IEC 62366-1 Edition 1.0 2015-02
- IEEE Std 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 VA30A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.