Siemens Healthcare GmbH
% Mr. Elango Rangappan
Regulatory Affairs Manager
Siemensstr. 1
Forchheim, 91301
GERMANY

July 1, 2020

Re: K201477
Trade/Device Name: syngo.via View&GO (Version VA20A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 27, 2020
Received: June 3, 2020

Dear Mr. Rangappan:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201477

Device Name
syngo.via View&GO (Version VA20A)

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 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.

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K201477

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: May 27, 2020

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

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3. **Device Name and Classification:**

Trade Name:	*syngo*.via View&GO (Version VA20A)
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 View&GO (Version VA10A)
510(k) Clearance:	K182208
Clearance Date:	Sept 7, 2018
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 Picture Archiving and Communications System, *syngo*.via View&GO, software version VA20A. This 510(k) submission describes several modifications to the previously cleared predicate device, *syngo*.via View&GO, software version VA10A.

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 VA20A, as well as the predicate device, *syngo*.via View&GO, software version VA10A.

6. 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.

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

The following table compares the functionality of *syngo*.via View&GO VA20A to the predicate device *syngo*.via View&GO VA10A:

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
Device name and version (K number)	***syngo*.via View&GO (Version VA20A)**	***syngo*.via View&GO VA10A (**K182202**)**	New product version	NA
Manufacturer	Siemens Healthcare GmbH	Siemens Healthcare GmbH	Same	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.	Same	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.	Same	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.	Same	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[19] ("Rib labeling") - Reprocessing X-ray projection images into 3D image and Topograms [17]	- 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[20] ("Rib labeling")	The reprocessing algorithms was been added to the existing algorithms in the subject device when compared to the predicate device	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 taken for the safety and effectiveness of the subject device
Quantitative algorithms	Distance, angle, VOI and ROI measurements	Distance, angle, VOI and ROI measurements	Same	NA

[19] Rib Labeling as a functionality was already covered by a 510(k) clearance with device *SYNGO*, CT BONE READING, K123584.
[20] Rib Labeling as a functionality was already covered by a 510(k) clearance with device *SYNGO*, CT BONE READING, K123584.
[17]Reprocessing algorithm as a functionality was already covered by the 510(k) clearance with device syngo X-Workplace SW VD10, K143319

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
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	Same	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: 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.	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.	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
	Supported Compressions for export: lossless compression algorithms, JPEG, JPEG 2000 and RLE.	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 7 – 64 bit SP1 Microsoft Windows 10 – 64 bit	Same. Note: In the subject device the Windows 7 Operating System supported only for updates.	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	Intimate the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating system compatibility check during Installation. Display Compatibility Check supports the end user to qualify the system for proper diagnostic use.	Intimate the user in case the data transfer is interrupted to the connected DICOM node. Hardware / Operating system compatibility check during Installation. Display Compatibility Check supports the end user to qualify the system for proper diagnostic use.	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
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.	Same	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.	Same	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	Same	NA
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.	Same.	NA
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.	Same	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.	Same	NA

	Subject device	Predicate device	Comparison	Impact to Safety & Effectiveness
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.	Same	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.	Same	NA
Ranges	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are supported. Additionally, Anatomical Range presets[21] can be created.	Yes, parallel, radial, Radial sliced, Curved and Spine ranges are supported. But Range presets are not supported.	In the subject device, additionally the Anatomical range presets are supported. Presets contain predefined anatomic values to indicate which related anatomical structure and body region is displayed and to help position the range as required.	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 taken for the safety and 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	Yes, with suggested spine labels to be confirmed by the user, and additional smart placement of labels, also in inter-vertebra regions, support of	Same	NA

[21] 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
	2D images, support of multi-series studies, and added support for rib labels.	2D images, support of multi-series studies, and added support for rib labels.		
Communication	Yes, Interface with DICOM is supported.	Yes, Interface with DICOM is supported.	Same	NA
Printing	Yes, both paper and DICOM printing supported.	Yes, only paper printing supported.	In the subject device print support added for DICOM printers in addition to the paper printers as in predicate 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 taken for the safety and effectiveness of the subject device.
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.	Same	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.	Same	NA

Table 13: 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 (2016) 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 VA20A, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.