



Siemens Medical Solutions USA, Inc.  
% Prithul Bom  
Most Responsible Person  
Regulatory Technology Services, LLC  
1000 Westgate Drive, Suite 510k  
SAINT PAUL MN 55114

May 20, 2022

Re: K220832  
Trade/Device Name: syngo Dynamics (Version VA40E)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical image management and processing system  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: May 9, 2022  
Received: May 10, 2022

Dear Prithul Bom:

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](mailto: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

## Indications for Use

510(k) Number (if known)

K220832

Device Name

syngo Dynamics (version VA40E)

Indications for Use (Describe)

syngo Dynamics is a multimodality, vendor agnostic Cardiology image and information system intended for medical image management and processing that provides capabilities relating to the review and digital processing of medical images.

syngo Dynamics supports clinicians by providing post image processing functions for image manipulation, and/or quantification that are intended for use in the interpretation and analysis of medical images for disease detection, diagnosis, and/or patient management within the healthcare institution's network.

syngo Dynamics is not intended to be used for display or diagnosis of digital mammography images 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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K220832

## 510(k) Summary

### *syngo* Dynamics (Version VA40E)

In accordance with 21 CFR §807.92, the following summary of safety and effectiveness is provided.

#### I. SUBMITTER

21CFR § 807.92(a)(1)

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Date Prepared: May 03, 2022

#### II. DEVICE

21CFR § 807.92(a)(2)

Device Trade Name	<i>syngo</i> Dynamics (version VA40E)
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Classification Panel	Radiology
Regulation Number	21 CFR §892.2050
Product Code	LLZ

#### III. LEGALLY MARKETED PREDICATE DEVICES

21CFR § 807.92(a)(3)

##### Predicate Device

Device Trade Name	<i>syngo</i> Dynamics Version VA30
510(k) Number	K171053
Product Code	LLZ

This predicate has not been subject to a design-related recall.

##### Reference Device

Device Trade Name	<i>syngo</i> .via (Version VB40A)
510(k) Number	K191040
Product Code	LLZ

This reference device has not been subject to a design-related recall.

**IV. DEVICE DESCRIPTION SUMMARY**

21CFR § 807.92(a)(4)

This premarket notification addresses the Siemens Healthineers syngo Dynamics (Version VA40E) Medical Image Management and Processing System (MIMPS).

*syngo* Dynamics is a software only medical device which is used with common IT hardware. Recommended configurations are defined for the hardware required to run the device, and hardware is not considered as part of the medical device.

*syngo* Dynamics is intended to be used by trained healthcare professionals in a professional healthcare facility to review, edit, and manipulate image data, as well as to generate quantitative data, qualitative data, and diagnostic reports.

*syngo* Dynamics is a digital image display and reporting system with flexible deployment – it can function as a standalone medical device that includes a DICOM Server or as an integrated module within an Electronic Health Record (EHR) System with a DICOM Archive that receives images from digital image acquisition devices such as ultrasound and x-ray angiography machines. There are three deployments: Standalone, EHR/EHS Integrated, and Multi-Modality Cardiovascular (MMCV). MMCV deployment functions as a standalone medical device with capability of natively support 2D and 3D CT and MR image types.

The use of *syngo* Dynamics is focused on cardiac ultrasound (echocardiography), angiography (x-ray), cardiac nuclear medicine (NM), CT and MR studies that cover both adult and pediatric medicine. Also supported is vascular ultrasound and ultrasound in Obstetrics/Gynecology and Maternal Fetal Medicine (fetal echocardiography during pregnancy).

*syngo* Dynamics is based on a client-server architecture. The *syngo* Dynamics server processes the data from the connected imaging modalities, and stores data and images to a DICOM server and routes them for permanent storage, printing, and review. The client provides the user interface for interactive image viewing, reporting, and processing; and can be installed on network connected workstations.

*syngo* Dynamics offers multiple access strategies: A Workplace that provides full functionality for reading and reporting; A Remote Workplace that provides additionally compressed images with access to full fidelity images for reading and reporting; and a browser based WebViewer that provides access to additionally compressed images and reports from compatible devices (including mobile devices).

In the United States, monitors (displays) should not be used for diagnosis, unless the monitor (display) has specifically received 510(k) clearance for this purpose.

**V. INTENDED USE/INDICATIONS FOR USE**

21CFR § 807.92(a)(5)

*syngo* Dynamics is a multimodality, vendor agnostic Cardiology image and information system intended for medical image management and processing that provides capabilities relating to the review and digital processing of medical images.

*syngo* Dynamics supports clinicians by providing post image processing functions for image manipulation, and/or quantification that are intended for use in the interpretation and analysis of medical images for disease detection, diagnosis, and/or patient management within the healthcare institution's network.

*syngo* Dynamics is not intended to be used for display or diagnosis of digital mammography images in the U.S.

**Indications for Use Comparison**

<p align="center"><b>Subject Device</b> <i>syngo</i> Dynamics VA40E</p>	<p align="center"><b>Predicate Device</b> <i>syngo</i> Dynamics VA30 K171053</p>
<p><i>syngo</i> Dynamics is a multimodality, vendor agnostic Cardiology image and information system intended for medical image management and processing that provides capabilities relating to the review and digital processing of medical images.</p> <p><i>syngo</i> Dynamics supports clinicians by providing post image processing functions for image manipulation, and/or quantification that are intended for use in the interpretation and analysis of medical images for disease detection, diagnosis, and/or patient management within the healthcare institution’s network.</p> <p><i>syngo</i> Dynamics is not intended to be used for display or diagnosis of digital mammography images in the U.S.</p>	<p><i>syngo</i> Dynamics is an image and information system intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including review, analysis, quantification and reporting.</p> <p>As a Cardiology PACS and information system, <i>syngo</i> Dynamics supports the physician in interpretation and evaluation of examinations within healthcare institutions, in particular, in Cardiology, Obstetrics and Gynecology or other departments.</p> <p><i>syngo</i> Dynamics is not intended to be used for displaying of digital mammography images for diagnosis in the U.S.</p>

The subject device, *syngo* Dynamics (Version VA40E) is a new version of the predicate device, *syngo* Dynamics VA30 (K171053). The Indications for Use for the subject device and the predicate device are equivalent. There were no fundamental changes to the device as a cardiology-focused information and imaging management software. The indications for use were updated to exclude functions such as “storage and display” of medical images as they are no longer fall within the definition of a medical device by the FDA.

Neither the subject nor the predicate device is indicated for any specific disease, condition, or patient population, and both are intended to support healthcare professionals in the healthcare institutions’ environment.

Both the subject and predicate devices share the same contraindication that they are not intended to be used for display or diagnosis of digital mammography images in the U.S.

**Indications for Use/Intended Use Comparison Summary and Conclusion**

The Indications for Use were assessed in accordance with the following FDA Guidance Documents:

- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
- Food and Drug Administration Staff Guidance for Industry, General/Specific Intended Use

The results of this evaluation determined that the Indications for Use for the subject device and the predicate device are fundamentally the same, and only includes minor updates. As such, Siemens Healthineers is of the opinion that the Intended Use and Indications for Use are similar to the predicate device.

**VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

21CFR § 807.92(a)(6)

Attribute	Subject Device <i>syngo</i> Dynamics VA40E	Predicate Device <i>syngo</i> Dynamics VA30 K171053	Equivalency Analysis
<b>Architecture</b>	Client-server	Client-server	Same
<b>Supported modalities</b>	<ul style="list-style-type: none"> <li>• US</li> <li>• XA</li> <li>• DX</li> <li>• CT</li> <li>• MR</li> <li>• SC</li> <li>• NM</li> </ul> Additionally through Corridor4DM: <ul style="list-style-type: none"> <li>• NM</li> <li>• PET</li> </ul>	<ul style="list-style-type: none"> <li>• US</li> <li>• XA</li> <li>• DX</li> <li>• DR</li> <li>• NM through Corridor4DM</li> </ul>	Subject device added support for a few DICOM modalities compared to the predicate device. Note: The subject device has the identical natively supported modalities as the reference device, <i>syngo</i> .via VB40A (K191040). The additionally supported modalities by the subject device only enhances and extends the conditions for use and it does not impact or change the purpose or the actual use of the device (intended use).
<b>Image Communication</b>	Within the network, the following communication protocols are used: <ul style="list-style-type: none"> <li>• TCP/IP for communication and transport</li> <li>• DICOM and HL7 at application level</li> <li>• HTTP(S) for communication and transport of images, MP4s and thumbnails</li> </ul>	Within the network, the following communication protocols are used: <ul style="list-style-type: none"> <li>• TCP/IP: for communication and transport</li> <li>• DICOM and HL7 at application level</li> <li>• HTTP for communication and transport of thumbnails</li> </ul>	Equivalent. All standard protocols.
<b>Image Data Compression</b>	Lossless compression with compression factor 2 to 3 and lossy compression (JPEG and MP4) with higher compression rate.	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate.	Equivalent. The only difference between the subject device and the predicate device is the file format.

Attribute	Subject Device <i>syngo Dynamics</i> VA40E	Predicate Device <i>syngo Dynamics</i> VA30 K171053	Equivalency Analysis
<b>Imaging Algorithms</b>	<ul style="list-style-type: none"> <li>• Window/Leveling</li> <li>• Edge Enhancement</li> <li>• Digital Subtraction</li> <li>• Multiplanar reconstruction (MPR)</li> <li>• Maximum and Minimum Intensity Projection (MIP/MinIP)</li> <li>• Volume Rendering Technique (VRT)</li> </ul>	<ul style="list-style-type: none"> <li>• Window/Leveling</li> <li>• Edge Enhancement</li> <li>• Digital Subtraction</li> </ul>	<p>The subject device uses the same imaging algorithm as the predicate device, with additional four imaging algorithms.</p> <p>Note: the additional imaging algorithms identical to that are implemented in the reference device, <i>syngo.via</i> VB40A (K191040).</p>
<b>Quantitative algorithms</b>	<ul style="list-style-type: none"> <li>• Pixel Size Evaluation</li> <li>• Distance line</li> <li>• Angle</li> <li>• Volume</li> </ul>	<ul style="list-style-type: none"> <li>• Pixel Size Evaluation</li> </ul>	<p>The subject device added three quantitative algorithms from the predicate device.</p> <p>Note: the additional quantitative algorithms identical to that are implemented in the reference device, <i>syngo.via</i> VB40A (K191040).</p>
<b>Decision Support</b>	<p>Ability to interface with a third-party rules engine (BizTalk), where rules are configured by the end customer to determine clinical relevance of selected observations.</p> <p>Customers identify and store selected patient data.</p> <p>Orchestrations provide a trigger to pull in previously stored relevant data for a given study.</p>	<p>Ability to interface with a third-party rules engine (BizTalk), where rules are configured by the end customer to determine clinical relevance of selected observations.</p> <p>Customers identify and store selected patient data.</p> <p>Orchestrations provides a trigger to pull in previously stored relevant data for a given study.</p>	<p>Same with the predicate device.</p>



Attribute	Subject Device <i>syngo Dynamics</i> VA40E	Predicate Device <i>syngo Dynamics</i> VA30 K171053	Equivalency Analysis
<b>Reporting</b>	<ul style="list-style-type: none"> <li>• Customizable DICOM Structured Reporting</li> <li>• Collaborative reporting</li> <li>• Remote reporting</li> </ul>	<ul style="list-style-type: none"> <li>• Customizable DICOM Structured Reporting</li> <li>• Collaborative reporting</li> <li>• Web reporting</li> </ul>	Equivalent to the predicate device. The web reporting using “Portal Image Review” in the predicate device was deprecated. In VA40E, remote reporting is accomplished through Remote Workplace.
<b>Access strategies for imaging and reporting</b>	<ul style="list-style-type: none"> <li>• Workplace (thick client) – access for reading and reporting.</li> <li>• Remote Workplace (MP4 image display with access to full DICOM image for US/XA and full DICOM image for CT/MR) – access for reading and reporting.</li> <li>• WebViewer- (Web Client with MP4 Image display) – Access for review only</li> </ul>	<ul style="list-style-type: none"> <li>• Workplace (thick client)- access for reading and reporting.</li> <li>• Portal – (Web Client for reading and reporting with limited functionality.)</li> </ul>	Similar to the predicate device. Instead of the Portal Image Review in the predicate device, the subject device has the Remote Workplace and the WebViewer.
<b>Mobile Device Support</b>	Yes – Through WebViewer, Supports iOS and Android devices, but non-diagnostic use.	Yes –Through the Common Login and Portal Image Review, images can be viewed on mobile devices, but are non-diagnostic.	Equivalent. Both devices use web client for read-only access.
<b>Long Term Archive</b>	Provide long term archive and retrieve of DICOM studies to/from either VNA (Vendor Neutral Archive) or HSM (Hierarchical Storage Management) archiving Systems.	Provide long term archive and retrieve of DICOM studies to/from either VNA (Vendor Neutral Archive) or HSM (Hierarchical Storage Management) archiving Systems.	Same.

Attribute	Subject Device <i>syngo</i> Dynamics VA40E	Predicate Device <i>syngo</i> Dynamics VA30 K171053	Equivalency Analysis
<b>Hardware</b>	Software-only option for server Workstation: software only (HW is not part of the medical device, but needs to meet recommended requirements as specified by <i>syngo</i> Dynamics)	Software-only option for server Workstation: software only (HW is not part of the medical device, but needs to meet recommended requirements as specified by <i>syngo</i> Dynamics)	Same.
<b>Virtualization</b>	Provides virtualization of server and client machines	Provides virtualization of server and client machines	Same.
<b>Operating system</b>	Server: Microsoft Windows server 2016 Standard edition (64 bit) Microsoft Windows Server 2019 Standard Edition (64 Bit) Client Software: Microsoft Windows 10 x64 version 1803 or greater Portal Website Host: Microsoft Windows Server 2016 Standard edition (64-bit), Microsoft Windows Server 2019 Standard edition (64-bit)	Server: Windows 2012 R2 Server Standard Edition R2 (64-bit) Portal Client: Windows 7 SP1 or higher (64-bit) Portal Website Host: Windows 2012 R2 Server Standard Edition R2 (64-bit)	Equivalent. Subject device uses updated versions of Microsoft OS.

Attribute	Subject Device <i>syngo</i> Dynamics VA40E	Predicate Device <i>syngo</i> Dynamics VA30 K171053	Equivalency Analysis
<b>Deployment strategy</b>	<ul style="list-style-type: none"> <li>• The use of <i>syngo</i> Dynamics VA40E server/workplace in the context of cardiovascular configuration.</li> <li>• EHR/EHS Integrated configuration with <i>syngo</i> Dynamics server.</li> <li>• Multi-modality cardiovascular configuration with native/<i>syngo</i> server and <i>syngo</i> Dynamics workplace with native/<i>syngo</i> components.</li> </ul>	<ul style="list-style-type: none"> <li>• The use of <i>syngo</i> Dynamics VA30 server/workplace in the context of cardiovascular configuration.</li> <li>• EHR/EHS Integrated configuration with <i>syngo</i> Dynamics server.</li> </ul>	<p>First two deployments are equivalent to the predicate device.</p> <p>Note: The third deployment uses identical technology to the reference device, <i>syngo</i>.via VB40A (K191040). The changes in the key attributes due to the addition of this deployment is covered above (Supported modalities, Imaging algorithms, Quantitative algorithms).</p> <p>Note: Multi-modality cardiovascular configuration additionally uses native/<i>syngo</i> software (NS_Container and NS_Frontend) in native/<i>syngo</i> server and workplace to support viewing of CT and MR studies. That's the same technology which is used in the reference device <i>syngo</i>.via VB40A (K191040).</p>

## VII. PERFORMANCE DATA

The following performance data were provided in support to demonstrate similarities to the predicate /previously cleared device.

### Clinical Testing

21CFR § 807.92(b)(1)

No clinical studies were carried out for *syngo* Dynamics (Version VA40E). All performance testing was conducted in a non-clinical fashion as part of the verification and validation activities for the medical device.

### Summary of Non-Clinical Testing

21CFR § 807.92(b)(2)

No performance standards for MIMPS have been issued under the authority of Section 514. Non-clinical testing was conducted for the device *syngo* Dynamics (Version VA40E) during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthineers claims conformance to the following recognized consensus standards:

- NEMA PS 3.1 - 3.20 (2016)
- ISO IEC 10918-1 First edition 1994-02-15
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION
- ISO 14971 Third Edition 2019-12
- IEEE Std 3333.2.1-2015
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC TR 80001-2-2 Edition 1.0 2012-07
- IEC 82304-1 Edition 1.0 2016-10

### Software Verification and Validation

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. Non-clinical Testing was conducted during product development. Evidence provided within this submission demonstrates conformance with special controls for medical devices containing software.

Cybersecurity considerations related to *syngo* Dynamics are included within this submission. Siemens Healthineers conforms to cybersecurity requirements by implementing a means to prevent unauthorized access, modification, misuse, denial of use or unauthorized use of information stored, accessed or transferred from a medical device to an external recipient.

Risk Analysis, in compliance with ISO 14971 Third Edition, for *syngo* Dynamics (Version VA40E) 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 in support to determine similarities to the predicate /previously cleared device.

## VIII. CONCLUSIONS

21CFR § 807.92(b)(3)

Performance tests were conducted to test the functionality of the device *syngo* Dynamics (Version VA40E). These tests have been performed to assess the functionality of the subject device. Results of all testing conducted were found acceptable in support to determine similarities to the predicate /previously cleared device.

Device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management was implemented throughout the development process to control potential hazards.

The device does not come in contact with the patient and is only used by trained professionals. The output of the device is evaluated by clinicians, providing for sufficient review to identify and intervene in the event of a malfunction.

Siemens Healthineers believes that *syngo* Dynamics (Version VA40E) is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

### **Substantial Equivalence Conclusion**

The comparison of intended use, technological characteristics, performance specifications, device hazards as well as verification and validation results demonstrate that *syngo* Dynamics is safe, effective and performs as well as the predicate device.

In summary, Siemens Healthineers is of the opinion that *syngo* Dynamics (Version VA40E) does not introduce any new significant potential safety risks and is similar to the predicate device.