Siemens Medical Solutions USA, Inc.
℅ Jiayan Liu
Regulatory Affairs Manager
400 W. Morgan Road
ANN ARBOR MI 48108

November 14, 2022

Re: K222428
Trade/Device Name: syngo Dynamics (Version VA40F)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: September 29, 2022
Received: October 4, 2022

Dear Jiayan Liu:

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)*

K222428

Device Name
syngo Dynamics (version VA40F)

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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K222428

510(k) Summary

syngo Dynamics (Version VA40F)

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

I. SUBMITTER

21CFR § 807.92(a)(1)

Siemens Medical Solutions USA, Inc.
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Contact Person: Jiayan Liu

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Date Prepared: November 7, 2022

II. DEVICE

21CFR § 807.92(a)(2)

Device Trade Name	*syngo* Dynamics (version VA40F)
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	QIH

III. LEGALLY MARKETED PREDICATE DEVICES

21CFR § 807.92(a)(3)

Predicate Device

Device Trade Name	*syngo* Dynamics (Version VA40E)
510(k) Number	K220832
Product Code	LLZ

This predicate 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 VA40F) 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 provides various semi-automated anatomical visualization tools.

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

Subject Device ***syngo* Dynamics VA40F**	**Predicate Device** ***syngo* Dynamics VA40E** **K220832**
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.	*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 healthcare institution's network. *syngo* Dynamics is not intended to be used for displaying of digital mammography images for diagnosis in the U.S.

The subject device, *syngo* Dynamics (Version VA40F) is a new version of the predicate device, *syngo* Dynamics VA40E (K220832). The Indications for Use for the subject device and the predicate device are identical. There were no fundamental changes to the device as a cardiology-focused information and imaging management software.

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 *syngo* Dynamics VA40F	Predicate Device *syngo* Dynamics VA40E K220832	Equivalency Analysis
Architecture	Client-server	Client-server	Identical
Supported modalities	• US • XA • DX • CT • MR • SC • NM • PT	• US • XA • DX • CT • MR • SC • NM • PT	Identical
Supported deployment	• Standalone medical device including a DICOM Server • Integrated model within an Electronic Health Record (EHR) System with a DICOM Archive • Multimodality Cardiovascular (MMCV) deployment with native support of 2D/3D CT/MR image types	• Standalone medical device including a DICOM Server • Integrated model within an Electronic Health Record (EHR) System with a DICOM Archive • Multimodality Cardiovascular (MMCV) deployment with native support of 2D/3D CT/MR image types	Identical
Image Communication	Within the network, the following communication protocols are used: • TCP/IP: for communication and transport • DICOM and HL7 at application level • HTTP for communication and transport of images, MP4s and thumbnails	Within the network, the following communication protocols are used: • TCP/IP for communication and transport • DICOM and HL7 at application level • HTTP(S) for communication and transport of images, MP4s and thumbnails	Identical
Image Data Compression	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 (JPEG and MP4) with higher compression rate.	Identical

Attribute	Subject Device *syngo* Dynamics VA40F	Predicate Device *syngo* Dynamics VA40E K220832	Equivalency Analysis
Imaging Algorithms	• Window/Leveling • Edge Enhancement • Digital Subtraction • Multiplanar reconstruction (MPR) • Maximum and Minimum Intensity Projection (MIP/MinIP) • Volume Rendering Technique (VRT) • Gamma Correction • Manual and semi-automated calculation for left ventricular ejection fraction (Auto EF)	• Window/Leveling • Edge Enhancement • Digital Subtraction • Multiplanar reconstruction (MPR) • Maximum and Minimum Intensity Projection (MIP/MinIP) • Volume Rendering Technique (VRT) • Gamma Correction • Manual calculation for left ventricular ejection fraction	Updated by adding semi-automated ejection fraction
Quantitative algorithms	• Pixel Size Evaluation • Distance line • Angle • volume	• Pixel Size Evaluation • Distance line • Angle • Volume	Identical
Decision Support	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. Customers identify and store selected patient data. Orchestrations provide a trigger to pull in previously stored relevant data for a given study.	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. Customers identify and store selected patient data. Orchestrations provide a trigger to pull in previously stored relevant data for a given study.	Identical
Reporting	• Customizable DICOM Structured Reporting • Collaborative reporting • Web reporting	• Customizable DICOM Structured Reporting • Collaborative reporting • Remote reporting	Identical

Attribute	Subject Device *syngo* Dynamics VA40F	Predicate Device *syngo* Dynamics VA40E K220832	Equivalency Analysis
Access strategies for imaging and reporting	• Workplace (thick client)- access for reading and reporting. • 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 • WebViewer – (Web Client with MP4 Image display) – Access for review only • Portal – (Web Client for reading and reporting with limited functionality.)	• Workplace (thick client) – access for reading and reporting. • 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. • WebViewer- (Web Client with MP4 Image display) – Access for review only	Similar. Additional portal access for review and limited functionality in subject device.
Mobile Device Support	Yes –Through the Common Login and Portal Image Review, images can be viewed on mobile devices, WebViewer, supports iOS and Android devices, but are non-diagnostic use.	Yes – Through WebViewer, Supports iOS and Android devices, but non-diagnostic use.	Similar. Additional portal access for review and limited functionality in subject device.
Long Term Archive	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.	Identical
Hardware	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 *syngo* 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 *syngo* Dynamics)	Identical
Virtualization	Provides virtualization of server and client machines	Provides virtualization of server and client machines	Identical

Attribute	Subject Device *syngo* Dynamics VA40F	Predicate Device *syngo* Dynamics VA40E K220832	Equivalency Analysis
Operating system	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)	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)	Identical
Deployment strategy	• The use of *syngo* Dynamics VA30 server/workplace in the context of cardiovascular configuration. • EHR/EHS Integrated configuration with *syngo* Dynamics server. • Multi-modality cardiovascular configuration with native/syngo server and syngo Dynamics workplace with native/syngo components.	• The use of *syngo* Dynamics VA40E server/workplace in the context of cardiovascular configuration. • EHR/EHS Integrated configuration with *syngo* Dynamics server. • Multi-modality cardiovascular configuration with native/syngo server and *syngo* Dynamics workplace with native/syngo components.	Identical

The functionalities of subject and predicate devices are fundamentally the same except for differences in image review features. Comparing with the predicate, the subject device is supplied with AI/ML algorithm that enable an optional semi-automated method (Auto EF) to calculate left ventricle ejection fraction using ultrasound images. Both subject and predicate devices have identical manual calculations

of left ventricular ejection fraction (LV EF). The subject device has an additional capability for semi-automated calculation of LV EF on images selected by the user and under full control of the user including possible manual intervention, performing equivalently to the manual measurement with no new concerns for the safety and effectiveness.

VII. PERFORMANCE DATA

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

Clinical Testing

21CFR § 807.92(b)(1)

No clinical studies were carried out for *syngo* Dynamics (Version VA40F). 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 VA40F) 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 VA40F) 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.

Validation Studies for AI/ML-enabled functions

Auto EF

To validate the syngo Dynamics (Version VA40F) Intended Use, standalone performance testing for Auto EF was conducted to assess the performance of Auto EF compared to the ground truth (reference standard) established using conventional methods.

The test data (n = 150) represent 3 sites in the U.S. with geographic diversity from 2 different regions and are independent of the training data used for the training of the Auto EF algorithm. The test data are representative of the intended use population for Auto EF. They are balanced for gender and cover an age range from 21 to 93 years (average 64 years). The BMI ranges from 16.5 to 48.8 with an average of 27.9. Three ultrasound manufacturers (Philips, GE and Siemens) are included in the testing. Cases across the range of cardiac function are included.

The ground truth was established by 2 experienced sonographers using a conventional manual method to establish left ventriular volumes and ejection fraction with the "Method of Disks" (MOD) also known as the Modified Simpson's Rule. The 2 sonographers worked independently of each other and did not have access to Auto EF when establishing the ground truth.

Acceptance of the statistical data is a Pearson's correlation coefficient $r \geq 0.800$ between the biplane EF generated by Auto EF and the ground truth. This acceptance criterion has been previously used for the purpose of evaluating left ventricular ejection fraction in FDA cleared products (K210053). Additional acceptance criteria were defined with a total of 12 predetermined acceptance criteria.

The Auto EF results are exceeding all 12 defined acceptance criteria. Biplane EF correlation was 0.827 between Auto EF and ground truth ($P<0.0001$).

The results of clinical data-based software validation for the subject device demonstrated equivalent performance in comparison to the reference generated using conventional manual analysis.

VIII. CONCLUSIONS

21CFR § 807.92(b)(3)

Performance tests were conducted to test the functionality of the device *syngo* Dynamics (Version VA40F). 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 VA40F) 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 VA40F) does not introduce any new significant potential safety risks and is similar to the predicate device.