April 10, 2026

Siemens Healthcare GmbH
Jiayan Liu
Regulatory Affairs Manager
Henkestr. 127
Erlanger, 91052
Germany

Re: K253689
Trade/Device Name: syngo Dynamics (VA41F)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 14, 2025
Received: March 9, 2026

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253689

Device Name
syngo Dynamics (VA41F)

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 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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K253689

510(k) Summary

syngo Dynamics (VA41F)

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: March 6th, 2026

II. DEVICE

21CFR § 807.92(a)(2)

Device Trade Name	*syngo* Dynamics (VA41F)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
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 VA41D)
510(k) Number	K242551
Product Code	QIH

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 VA41F) 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 two flexible deployments – 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.

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	Predicate Device

***syngo* Dynamics VA41F**	***syngo* Dynamics VA41D K242551**
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 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 display or diagnosis of digital mammography images in the U.S.

The subject device, *syngo* Dynamics (Version VA41F) is a new version of the predicate device, *syngo* Dynamics VA41D (K242551). 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. 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 VA41F	Predicate Device *syngo* Dynamics VA41D K242551	Equivalency Analysis
Architecture	Client-server	Client-server	Identical
Supported modalities	• US • XA • DX • CT • MR • SC • NM • PT • ECG	• US • XA • DX • CT • MR • SC • NM • PT • ECG	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 VA41F	Predicate Device *syngo* Dynamics VA41D K242551	Equivalency Analysis
Imaging Algorithms	• Window/Leveling • Edge Enhancement • Digital Subtraction • Gamma Correction • Manual and semi-automated calculation for left ventricular ejection fraction (Auto EF, updated) • View Classification Labels – manual & AI/ML based (Extended View Classification) • Manual and semi-automated measurements (Auto Measures)	• 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)	Different. The new AI-enabled tools in subject device enhance the existing functions in the predicate device. Removal of 2D/3D visualization functions do not impact current syngo Dynamics offering to the users.
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 VA41F	Predicate Device *syngo* Dynamics VA41D K242551	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) – access for reading and reporting • WebViewer – (Web Client with MP4 Image display) – Access for review only	• 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	Different. Removal of Multi-modality cardiovascular configuration does not impact current syngo Dynamics offering to the users.
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 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.	Identical
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 VA41F	Predicate Device *syngo* Dynamics VA41D K242551	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: 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)	Identical
Deployment strategy	• The use of *syngo* Dynamics VA41F server/workplace in the context of cardiovascular configuration. • EHR/EHS Integrated configuration with *syngo* Dynamics server.	• The use of *syngo* Dynamics VA41D 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.	Different. Removal of Multi-modality cardiovascular configuration does not impact current syngo Dynamics offering to the users.

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 VA41F). 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 VA41F) 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 (2023e)
- 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 "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, documentation is included within this submission for software of Basic Documentation Level. 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 VA41F) 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

syngo Dynamics VA41F includes three AI/ML-enabled device software functions, which operate independently from each other.

Auto EF

The Auto EF tool provides a semi-automated measurement of left ventricular ejection fraction and volumes in apical 4 and 2 chamber views in adult transthoracic echocardiography exams. The core Auto EF algorithms in the subject device are unchanged from the predicate device.

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 ventricular 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.

The Auto EF results are exceeding all defined acceptance criteria. Auto EF has biplane results 140 of 150 cases (93.3%) with the current version. Biplane EF correlation was 0.822 between Auto EF and ground truth. The bias is minimal with -0.2% absolute EF. The coverage plot shows that the absolute biplane EF delta between Auto EF and GT is ≤10% EF units in 87.9% of cases.

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.

Auto Measures

The Auto Measures tool provides semi-automated measurements for 8 Measurement Groups in adult transthoracic echocardiography exams. Standalone performance testing was conducted to assess the performance of Auto Measures compared to the ground truth (reference standard) established using conventional methods. The following Measurement Groups are supported:

- PLAX 2D
- MV Inflow
- AoV Systolic Flow
- LVOT Systolic Flow
- MR Flow
- MV VTI
- PV Systolic Flow
- TR Flow

The data for Auto Measure bench testing represent 3 sites in the U.S. with geographic diversity from 2 different regions. They are balanced for gender and cover the age range of the intended use population. Three ultrasound manufacturers (Philips, GE and Siemens) are included in the testing with at least 25% representation. Each Measurement Group has a test set consisting of 150 images from unique patients.

The ground truth was established by 2 experienced sonographers.

The Auto Measure results are exceeding all predefined acceptance criteria.

Extended View Classification

Extended View Classification (EVC) processes 2D B-mode clips from transthoracic echocardiography studies and assigns view classification labels to supported clips.

Standalone performance testing for EVC was conducted to assess the performance of EVC compared to the ground truth (reference standard).

The test data consisted of transthoracic echocardiography studies including studies without and with contrast. The test data represent 3 sites in the U.S. with geographic diversity from 2 different regions and are independent of the data used for training of the EVC algorithm. The test data are representative of the intended use population for EVC. They are balanced for gender and cover an age range from 21 to 93 years (average 66 years). The BMI ranges from 13.5 to 52.7 with an average of 29.5. 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 clinical review using a manual method to label images. Predefined acceptance criteria were established for EVC performance, including requirements for successful processing of supported clips and overall view classification accuracy relative to the ground truth. The EVC algorithm met or exceeded all predefined acceptance criteria.

The results of standalone non-clinical bench testing demonstrate that EVC provides reliable view classification labeling and performs as intended for use as a workflow aid in transthoracic echocardiography image review. The test results are provided in the Instructions for Use.

VIII. Predetermined Change Control Plan

Siemens Healthineers will make future algorithm improvements under Predetermined Change Control Plans (PCCPs) for the three AI-DSFs in syngo Dynamics VA41F:

- Auto EF
- Auto Measures
- Extended View Classification

Each PCCP specifies anticipated modifications to the device software. The PCCP also specifies the methods to implement those modifications so that the device remains as safe and as effective as the predicate device.

The detailed description of the modifications, testing methods, validation activities, performance requirements, and communication to users are summarized in the tables below for the three AI/ML algorithms, respectively.

Summary Predetermined Modifications for Auto EF

Planned Modifications	Test Methods and Validation Activities	Communication to users, as needed
Modification Group #1: Re-training Auto EF with additional data	Performance testing will be repeated using the same test methods and acceptance criteria as that used in syngo Dynamics VA41F.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's re-training process and performance capabilities

Modification Group #2: Optimizations of the Auto EF core algorithms	Performance testing will be repeated using the same test methods and acceptance criteria as that used in syngo Dynamics VA41F.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's re-training process and performance capabilities
Modification Group #3: Auto EF with contrast support	Performance testing will be performed using the same test methods as in syngo Dynamics VA41F and predefined acceptance criteria.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's capabilities with expanded input image types

Summary Predetermined Modifications for Auto Measures

Planned Modifications	**Test Methods and Validation Activities**	**Communication to users, as needed**
Modification Group #1: Modifications to existing Auto Measures	Performance testing will be repeated using the same test methods and acceptance criteria as that used in syngo Dynamics VA41F.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's re-training process and performance capabilities
Modification Group #2: Adding new Auto Measures	Performance testing will be performed using the same test methods as in syngo Dynamics VA41F and predefined acceptance criteria.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's capabilities with expanded input and output data types

Summary Predetermined Modifications for EVC

Planned Modifications	**Test Methods and Validation Activities**	**Communication to users, as needed**
Modification Group #1: Re-training EVC with additional data	Performance testing will be repeated using the same test methods and acceptance criteria as that used in *syngo* Dynamics VA41F.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's re-training process and performance capabilities
Modification Group #2: Additional EVC inputs and outputs	Performance testing will be performed using the same test methods as in *syngo* Dynamics VA41F and predefined acceptance criteria.	Labeling will be updated in accordance with the authorized PCCP to provide users with current information regarding the device's capabilities with expanded input and output data types

IX. CONCLUSIONS

21CFR § 807.92(b)(3)

Performance tests were conducted to test the functionality of the device *syngo* Dynamics (Version VA41F). 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 VA41F) 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 VA41F) does not introduce any new significant potential safety risks and is substantially equivalent to the predicate device.