April 29, 2026

Siemens Medical Solutions USA, Inc.
% Patricia Jones
Regulatory Affairs Professional
40 Liberty Blvd.
MALVERN, PA 19355

Re: K254184
Trade/Device Name: syngo Application Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: December 23, 2025
Received: March 23, 2026

Dear Patricia Jones:

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.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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)*
K254184

Device Name
syngo Application Software

Indications for Use *(Describe)*
The syngo Application Software is a medical software for real-time viewing, image manipulation, 3Dvisualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and postprocessing and for viewing and postprocessing during interventional procedures.

The syngo Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, postprocessing, and reporting workstation. It can also be configured within a network to send and receive DICOM data.

Furthermore, the syngo Application Software can be deployed on systems of the Siemens Healthineers Angiography system family.

It provides image guided solutions in the operating room, for image guided surgery, by image fusion and by navigation systems, image guided solutions in interventional cardiology and electrophysiology and image guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The syngo Application Software can also be combined with fluoroscopy systems or radiographic systems. The syngo Application Software can be configured with a variety of syngo or Windows-based software options, which are intended to assist the physician in diagnosis, treatment planning and treatment control. It includes commercially available postprocessing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: *syngo* Application Software
510(k) #: K254184

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard,
Malvern, PA 19355

Date of Preparation: April 27, 2026
This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Systems USA, Inc.
40 Liberty Boulevard,
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
Siemens Healthineers AG
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number:
3004977335

2. Contact Person:

Ms. Patricia D Jones
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Phone: (678) 575-8832
Email: patricia.jones@siemens-healthineers.com

3. Device Name and Classification:

Trade Name:	*syngo* Application Software
Classification Name:	Medical Image Management and Processing System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.2050
Device Class:	Class II
Product Code:	QIH

4. Legally Marketed Predicate Device

Trade Name:	*syngo* Application Software
510(k) Clearance	K241569
Clearance Date	10/11/2024

Classification Name:	Medical Image Management and Processing System
Classification Panel:	Radiology
Classification Regulation:	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:

The "*syngo* Application Software" is medical diagnostic software for real-time viewing, diagnostic review, post-processing image manipulation, optimization, communication, reporting, and storage of medical images and data on exchange media. It provides image-guided solutions in the operating room, for image-guided surgery, by Image Fusion and by navigation systems, image-guided solutions in interventional cardiology and electrophysiology, and image-guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology. It can be deployed with a variety of *syngo* or Windows-based software options, which are intended to assist the physician in the evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens "*syngo* Application Software" is designed to work with digital radiographic, fluoroscopic, interventional, and angiographic systems.

Siemens Medical Solutions USA, Inc. hereby submits this Traditional 510(k) to request clearance to market the following modifications:

List of Modifications:

1) Updated Software VE40C to VE51A
   - A. New Updated myScrew Path Assist
   - B. Updated syngo Embolization Guidance user interface
   - C. Updated syngo TrueFusion
   - D. New feature "CleanEdge"
   - E. New syngo DynaCT Bone Removal
   - F. New syngo DynaCT MORE
   - G. Updated Contour Enhanced Overlay
   - H. Updated QuantWeb and 3D volumes feature for visual display on ARTIS Touch UI

2). Product Claims List

The "*syngo* Application Software" may be installed either on Siemens released PC hardware, on Siemens X-ray systems, or on Siemens angiography systems. The "*syngo* Application Software" is within the same classification regulation and the intended use and the general Indications for Use Statement for Siemens' Medical Image Management and Processing System remains the same

6. Indications for Use:

The *syngo* Application Software is a medical software for real-time viewing, image manipulation, 3D visualization, communication, and storage of medical images and data on exchange media. It is used for diagnostic image viewing and postprocessing and for viewing and postprocessing during interventional procedures.

The *syngo* Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, postprocessing, and reporting workstation. It can also be configured within a network to send and receive DICOM data.

Furthermore, the *syngo* Application Software can be deployed on systems of the Siemens Healthineers Angiography system family. It provides image-guided solutions in the operating room, for image-guided surgery, by image fusion and by navigation systems, image-guided solutions in interventional cardiology and electrophysiology, and image-guided solutions for interventional oncology, interventional radiology, and interventional neuroradiology.

The *syngo* Application Software can also be combined with fluoroscopy systems or radiographic systems.

The *syngo* Application Software can be configured with a variety of *syngo* or Windows-based software options, which are intended to assist the physician in the diagnosis, treatment planning, and treatment control. It includes commercially available postprocessing techniques and OEM options.

Procedures that can be performed include: minimally invasive surgical procedures and minimally invasive tumor treatment.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The subject device has the same intended use as the predicate device. Besides the proposed device modifications, the Subject Device has the same functionality and technology.

All software components of the subject device are the same as the ones from the predicate device except for the new optional software applications as presented in the table below:

The Subject Device modifications do not alter the fundamental scientific technology from the 510(k) cleared predicate device Siemens' "*syngo* Application Software" (VE40C), K241569.

Modifications	Subject Device *syngo* Application Software (VE51A)	Predicate Device *syngo* Application Software (VE40C) K241569	Comparison Results
New System Software/ Changes	1. Updated *syngo* Application Software from VE40C to VE51A	*syngo* Application Software VE40C	The VE51 Software contains new /updated features A-H.
	A. New Updated myScrew Path Assist	N/A	The New Updated myScrew Path Assist is a medical software module intended to be used primarily by spine surgeons to facilitate the placement of devices such as screws and K-wires in the patients' spine pedicles for a range of different indications.
	B. Updated syngo Embolization Guidance user interface	*syngo* Embolization Guidance	1. Interactive display of target measurements (diameter and volume) 2.Updated user interface designed with focus on clinical ease-of-use 3.Three workflows addressing specific clinical use-cases 4. Centerline color scheme visually linking targets with respective feeders.
	C. Updated syngo TrueFusion	*syngo* TrueFusion	1.The communication between ultrasound and angiography systems complies with IT requirements and is secured using a valid SSL/TLS certificate issued by a trusted Certificate Authority (CA). TLS version 1.3 is set as the minimum supported version. 2.The fused image is displayed directly on the ultrasound system screen, allowing the echocardiographer to view both the ultrasound and TrueFusion overlay simultaneously
	D. New feature "CleanEdge"	N/A	Postprocessing option for head DynaCT volume data. It reduces noise and high frequency artifacts in 3D head data by a non-linear smoothing filter.
	E. New syngo DynaCT Bone Removal	N/A	Provides automatic calculation and cropping of bony structure from thoracic, abdominal, and pelvic syngo DynaCT volume datasets of adult patients
	F. New syngo DynaCT MORE	N/A	syngo DynaCT MORE is intended to estimate the motion using the acquired image data

Modifications	Subject Device *syngo* Application Software (VE51A)	Predicate Device *syngo* Application Software (VE40C) K241569	Comparison Results
			and to compensate the motion during the 3D reconstruction
	G. Updated Contour Enhanced Overlay	Contour Enhanced Overlay	The Contour Enhanced Overlay parameter set within the "Light Enhancement Features" has been added to the preset gallery for VRT images.
	H. Updated QuantWeb and 3D volumes feature for visual display on ARTIS Touch UI	QuantWeb and 3D volumes	Quantweb is now accessible by tableside using the ARTIS Touch Interface. VE51A software also enables direct interaction with 3D volumes via touch User Interface.
	2. Product Claims List		

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the "*syngo* Application Software" during product development.

Siemens claims conformance to the following performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-125	General	Medical devices - Application of risk management to medical devices	14971	2019	ISO
5-134	General	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	15223-1	2021	ISO
5-135	General	Medical devices -Information to be supplied by the manufacturer	20417-First edition 2021-04 Corrected version 2021-12	2021	ISO
13-97	Software/ Informatics	Health software - Part 1: General requirements for product safety	82304-1	2016	IEC
13-79	Software/ Informatics	Medical Device Software - Software life-cycle process	62304	2015	IEC

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
5-129	General	Medical devices - Part 1 Application of usability engineering to medical devices	62366-1	2020	IEC
13-38	Software/ Informatics	Application of risk management for IT - networks incorporating medical devices - Part 1: Roles, responsibilities, and activities	80001-1	2010	IEC
13-122	Software/ Informatics	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle	81001-5-1	2021	IEC
12-363	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20 2024e	2024	NEMA
13-96	Software/ Informatics	Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements	2900-1	2017	ANSI UL
13-104	Software/ Informatics	Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems	2900-2-1	2017	ANSI UL
13-83	Software/ Informatics	Principles for medical device security – Risk management	TIR57	2016	AAMI
13-143	Software/ Informatics	Guidance on the use of AGILE practices in the development of medical device software	TIR45	2023	AAMI
13-131	Software/ Informatics	Standard for medical device security – Security risk management for device manufacturers	SW96	2023	ANSI AAMI

The modifications described in this Premarket Notification are supported with verification and validation testing.

Software Verification and Validation:
Software documentation for a **Basic Documentation Level** software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. Non-clinical tests were conducted on "*syngo* Application Software" during product development.

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

The Human Factor Usability Validation showed no safety-relevant functions that need to be validated with a summative usability validation according to the IEC and FDA Guidelines. "*syngo* Application Software" is safe and effective for intended users, uses, and use environments through the design control verification and validation process. No further risk mitigations are necessary.

Siemens 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. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1:2010 is the hospital. Provided in the Software Section is the required cybersecurity information.

Summary of Performance Testing Data:
Tests were conducted in support of the new/updated functionalities for the "*syngo* Application Software":

New Updated myScrew Path Assist testing encompassed basic functional aspects of 3D3D lab registration; acquisition wizard, 3D calibration process, image flip and name of vertebra, image capture functionality with overlay assist, basic flow screw planning, and basic flow spine guidance.

The updated *syngo* Embolization Guidance workflow was tested to validate that myEmbolization Guide provides semi-automatic identification of target structures, feeder vessels, and supports precise device navigation for embolization by overlaying planning information.

Updated syngo TrueFusion workflow was tested to check for overlay on live 2D image on the ultrasound and vice versa and checks that probe markers are considered for probe registration.

New feature "CleanEdge" was tested to ensure Interactive reconstruction is performed using the Clean Edge functionality to reduce the white noise and the edges of the structures are clear with focus on usage of the Image Correction Algorithms for different

system and detector types, and checks that CleanEdge functionality is only available for specific reconstruction mode.

New syngo DynaCT Bone Removal:
Quantitative segmentation accuracy was assessed through voxel-wise comparison of AI-generated bone masks against expert reference (ground truth) bone masks. Ground truth masks were created for 180 test cases. The test cohort was balanced by anatomical region, comprising 60 cases each for the thorax, abdomen, and pelvis.

AI-generated bone masks were compared voxel-wise with the expert reference masks to calculate overlap-based segmentation accuracy metrics. Quantitative results demonstrated close agreement with expert delineations, achieving a mean Dice similarity coefficient of approximately 0.95 ± 0.02 and a mean intersection-over-union (IoU) of approximately 0.90 ± 0.03 across the 180-case test set.

In addition to quantitative metrics, a clinical reader evaluation was conducted on 370 datasets acquired in the United States and Europe. Subgroup analyses were performed based on gender, age, body mass index (BMI), patient size, and data source. The clinical validation demonstrated an overall bone mask success rate of 100% (370/370 datasets), based on merged reader assessments. Furthermore, an overall vessel assessment improvement rate of 100% (304/304 contrast-enhanced datasets) was observed, as determined by majority reader vote.

In conclusion, these quantitative and clinical evaluation results support that the AI-generated bone masks are complete and reliable and that their use improves vessel assessment within the intended anatomical regions.

New syngo DynaCT MORE:
A retrospective comparative assessment of image quality and diagnostic utility was performed by clinical experts using DynaCT acquisitions reconstructed with and without syngo DynaCT MORE. A total of 40 liver datasets were included in the analysis. Data from both female and male patients were evaluated. The mean patient age was 69 ± 10 years, with an age range of 30 to 85 years. Body mass index (BMI) was available for 18 datasets and ranged from 16.5 to 45.2.

For the primary analysis, the acceptance rate for final image quality and diagnostic utility was evaluated. For each dataset, two independent readers assessed whether image quality and diagnostic utility after reconstruction with syngo DynaCT MORE were basically inferior (score 1), basically equivalent (score 2), or obviously better (score 3) compared with a conventional reconstruction. Sufficient image quality and diagnostic utility were defined as both readers rating each dataset as non-inferior (score 2 or 3). Based on the observed data, all 40 datasets were rated as non-inferior by both readers, resulting in an acceptance rate of 100%. Therefore, the predefined primary acceptance criterion was met.

For the secondary and further analyses, image sharpness, image contrast, artifact occurrence, and diagnostic confidence after reconstruction with syngo DynaCT MORE

were assessed in comparison with a conventional reconstruction using a 5-point rating scale. No inferior ratings (scores 1 or 2) were assigned for any of the evaluated parameters across all assessments. Furthermore, after reconstruction with syngo DynaCT MORE, no loss of anatomical structures was identified by the readers in any of the 120 assessments.
In conclusion, the acceptance criteria were met for both the primary and secondary analyses

Updated Contour Enhanced Overlay workflow was tested to achieve an optimal visualization of the overlay by adjusting contour enhancement functionality.

Updated QuantWeb and 3D volumes feature for visual display on ARTIS Touch UI workflow was tested to validate that Quant functionality is available and fully functional on the system and can be operated via control room and exam room on ARTIS Touch UI.

Performance tests were conducted to test the functionality of the "*syngo* Application Software. The results of all conducted testing were found acceptable and did not raise any new issues of safety or effectiveness.

All software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device that is currently marketed for the same intended use.

9. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device safely and effectively.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluation and post-processing of medical images.

10. Conclusion as to Substantial Equivalence:

The comparison of technological characteristics, non-clinical performance data, clinical images, and software validation data demonstrates that the subject device is substantially equivalent to the predicate device that is currently marketed for the same intended use.