



October 11, 2024

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

Re: K241569

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: LLZ
Dated: May 31, 2024
Received: May 31, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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).

Smita Katar

Lu Jiang
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Enclosure

Indications for Use

Submission Number (if known)

K241569

Device Name

syngo Application Software

Indications for Use (Describe)

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 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) #: K241569

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

Date of Preparation: October 11, 2024

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SDMA 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 Healthcare GmbH
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
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Email: patricia.jones@siemens-healthineers.com

3. Device Name and Classification:

Trade Name:	<i>syngo</i> 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:	LLZ

4. Legally Marketed Predicate Device

Trade Name:	<i>syngo</i> Application Software
510(k) Clearance	K230955
Clearance Date	12/20/2023

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:

1. Updated Software VE30A to VE40C
 - A. Updated myNeedle Guide “Progress Needle” steps with an additional “couple A+B” button (Software feature for ARTIS icono biplane only)
 - B. Updated *syngo* Biplane 3D Roadmap feature
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 except for a minor grammatical change (inclusion of “Healthineers”).

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. Therefore the subject device is considered substantially equivalent to the commercially available Siemens' "*syngo* Application Software" (VE30).

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:

Modifications	Subject Device <i>syngo</i> Application Software	Predicate Device <i>syngo</i> Application Software (VE30A) K230955	Comparison Results
New System Software/ Changes	1. Updated <i>syngo</i> Application Software from VE30A to VE40C	<i>syngo</i> Application Software	Modified: Software VE40C was updated to support modifications 1A & B. All Software modifications conform to "Guidance for the Content of Premarket Submissions for Device Software
	A. Updated myNeedle Guide "Progress Needle" steps with an additional "couple A+B" button (Software feature	<i>syngo</i> myNeedle Guide	

Modifications	Subject Device <i>syngo</i> Application Software	Predicate Device <i>syngo</i> Application Software (VE30A) K230955	Comparison Results
	for ARTIS icono biplane only)		Functions"". Provided in the software section of eStar is all required software testing per software guidance "Basic Level".
	B. Updated <i>syngo</i> Biplane 3D Roadmap feature	<i>syngo</i> 3D Roadmap	Provided in the Non-Clinical Testing Section of eStar are Bench Test Summaries. Bench tests were conducted and 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. All test results met all acceptance criteria.

The Subject Device modifications do not alter the fundamental scientific technology from the 510(k) cleared predicate device Siemens' "*syngo* Application Software" (VE30A), K230955.

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	15223-1	2021	ISO

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
		information to be supplied - Part 1: General requirements			
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
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
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
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1	2022	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	2900-2-1	2017	ANSI UL

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
		Components of Healthcare and Wellness Systems			

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

Software Verification and Validation:

Software documentation for a **Basic Level of Concern** 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": Updated myNeedle Guide testing encompassed Biplane-Couple-A-B, Invoke Progress Needle Step; Only Messages Progress Needle No Needle or Registration; Switch Off Drive To BE-PV; and Switch Off Drive To BE-PV-Biplane Bulls Eye View-Biplane. Updated syngo Biplane 3D Roadmap testing encompassed: Overlay internal datasets biplane; Biplane Overlay Contour from VRT on Monitor of the Biplane Overlay 3DGraphics on Monitor; Alternative Flow Biplane; 2D/2D 3D Registration OV Basic Flow Overlay Assist Biplane; Overlay Assist Set Active Plane; and 2D2D3D Biplane Registration Modes Segment Selection. After transfer and integration, the SW/System

will be carried out within the framework of SOP406 “Software Development” and cover compliance with IEC 62304.

Performance tests were conducted to test the functionality of the “*syngo* Application Software. These tests have been performed to assess the functionality of the Subject Device. 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.

Performance Verification/Validation & Test Report Summaries:

All updated and new *syngo* Application software features performance functionality has been tested and validated.

In summary, All conducted test results passed. Software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device.

The comparison of technological characteristics, non-clinical performance data, Human Factor Usability data, and 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 predicate device “*syngo* Application Software” (VE30A), K230955, was cleared based on non-clinical supportive information. Similar non-clinical test results demonstrate that the subject device’s “*syngo* Application Software” acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data, clinical images, and 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.