August 16, 2022

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

Re: K220433
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: July 7, 2022
Received: July 11, 2022

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 (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,

Laurel Burk, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220433

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 post processing and for viewing and post processing during interventional procedures.

The syngo Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, 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 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 post-processing techniques and OEM options.

Procedures that can be performed includes 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 (VE21)

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

Date of Preparation: August 11, 2022

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 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, 65-1A
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:	LLZ

4. Legally Marketed Predicate Device

Trade Name:	*syngo* Application Software
510(k) Clearance	K190780
Clearance Date	09/12/2019

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" (VE21) 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 evaluation of digital radiographic examinations, including diagnosis and/or treatment planning.

Siemens "*syngo* Application Software" (VE21) is designed to work with digital radiographic, fluoroscopic, interventional, and angiographic systems.

Siemens Medical Solutions USA, Inc. hereby submits this 510(k) to request clearance to market the updated optional post-processing software feature: **1)** Updated *syngo* TrueFusion; and **2)** Updated 510(k) Information for the predicate device**.** The updated feature is included in this submission for *syngo* Application Software (VE21).

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" (VE21) is within the same classification regulation and the intended use and the general Indications for Use Statement for Siemens' Picture Archiving and Communications 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 post processing and for viewing and post processing during interventional procedures.

The *syngo* Application Software can be deployed on independent hardware such as a stand-alone diagnostic review, post-processing, 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 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 post-processing techniques and OEM options.

Procedures that can be performed includes 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" (VE20).

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:

Property	**Subject Device:** "*syngo* Application Software" (VE21)	**Predicate Device:** "*syngo* Application Software" (VE20) (K190780)
Updated Software-Applications	1.. Updated *syngo* Application Software (VE21)	Updated *syngo* Application Software (VE20)
Comparison Results	**Modified:** *syngo* Application Software version (VE21) was updated to include: • *syngo* TrueFusion has been updated so that ultrasound B-mode and color doppler images can continuously be overlaid onto fluoroscopy images. In the previous software it was only possible to overlay ultrasound landmarks and heart valve models. The *syngo* TrueFusion (VE21) conforms to FDA Software Guidance document. 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.	

Update 510(k Information	2. Updated 510(k) information for the predicate device contains the following features approved via the internal non-filing justification process, which are applicable to the subject device are: • 3rd Party Software name change from Quant to QuantWeb • Added "Send to Quant" button • Name change from *syngo* Needle Guidance to myNeedle Guide
Comparison Results	The above listed non-filing justifications were considered comparable and approved as additional modifications post 510(k) clearance and used as the selected predicate for the Subject Device. 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.

The Subject Device modifications do not alter the fundamental scientific technology from the 510(k) cleared predicate device Siemens' "*syngo* Application Software" (VE20), K190780.

8. Nonclinical Performance Testing:

Non-clinical tests were conducted for the "*syngo* Application Software" (VE21) 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, labelling, 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

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
13-38	Software/ Informatics	Application of risk management for IT - networks incorporating medical devices - Part 1: Roles, responsibilities, and activities	80001-1	2010	IEC
13-96	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

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

Software Verification and Validation:
Software documentation for a **Moderate Level of Concern** software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, 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" (VE21) during product development.

The Risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. Testing for verification and validation for 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" (VE21) has been found to be 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 the performance Testing Data:
The following test were conducted in support of the updated *syngo* TrueFusion modification: Overlay Images Volume and Overlay Image Change Stand X-ray. The test results passed and concluded that the *syngo* TrueFusion image overlay functionality corresponds to the clinical workflow to utilize ultrasound images with X-ray image information.

Performance tests were conducted to test the functionality of the "*syngo* Application Software" (VE21). These tests have been performed to assess the functionality of the Subject Device. Results of all conducted testing were found acceptable and do 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:
The updated *syngo* Application software feature "*syngo* TrueFusion" performance functionality has been tested and validated.

In summary, the following conducted testing: Overlay Images Volume and Overlay Image Change Stand X-ray verifies that the ultrasound images were sent from US system and that the US image overlay is working if the stand parameters of the imaging system change and / or if X-ray is acquired. All conducted test result passed. Software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Device.

The comparison of technological characteristic, 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 in a safe and effective manner. 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 health care professionals familiar with and responsible for the evaluating and post processing of medical images.

10. Conclusion as to Substantial Equivalence:

The predicate device "*syngo* Application Software" (VE20), K190780, was cleared based on non-clinical supportive information. Similar non-clinical test results demonstrate that the subject device "*syngo* Application Software" (VE21) acceptance criteria are adequate for the intended use of the device. The comparison of technological characteristic, non-clinical performance 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.