Siemens Medical Solutions, USA, Inc.
% Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
685 East Middlefield Road
MOUNTAIN VIEW CA 94043

May 18, 2020

Re: K201062
Trade/Device Name: syngo Ultrasound Apps Suite™ (sUSAS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 17, 2020
Received: April 21, 2020

Dear Ms. Dunbar:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201062

Device Name
syngo® Ultrasound Apps. Suite™ (sUSAS)

Indications for Use *(Describe)*

The syngo® Ultrasound Apps Suite is a software-only product to be run on a user's PACS (Picture Archiving and Communications System) workstation. It is intended to launch Siemens' CAPs (Clinical Applications Packages) for image processing, including the acceptance, transfer, display and digital processing of ultrasound images. Digital processing includes image manipulation and quantification on a workstation. Use of a clinical application package by a qualified clinician can add information to the study to be used for a clinical diagnosis.

The software supports the following clinical application packages:
- eSie Volume Viewer
- eSie LVA
- eSie PISA
- eSie Valves

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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1.1.3 510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21CFR §807.92(c)

Date prepared: May 04, 2020

Part 1. Sponsor:
Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person:
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Siemens Medical Solutions USA, Inc.,
Ultrasound Division
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Mountain View, California 94043
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Part 2. Device Name: *syngo*® Ultrasound Apps Suite™ (sUSAS)

Common Name: System, Image Processing, Radiological

Classification Name: Picture Archiving and Communications System

Classification: Regulatory Class: II
Review Category: Tier II

Classification Panel Radiology

CFR Section 21 CFR §892.2050

Product Code 90-LLZ

Legal Manufacturer:
Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Part 3. Legally Marketed Predicate Devices

The *syngo*® Ultrasound Apps Suite™ (sUSAS) as described in this 510(k) submission is substantially equivalent to the company's legally marketed device, the eSie Apps Suite as represented below:

Primary Predicate Device	**510(k) Number / Clearance Date / ProCode**	**Substantial Equivalence claimed to:**
eSie Apps Suite (*Primary Predicate*)	K143254 / 12/10/2014 / LLZ	*Syngo*® Ultrasound Apps Suite VA17A image display, manipulation, post-processing with Clinical Applications Packages (CAPS) • Volume Review • eSie LVA • eSie PISA • eSie Valves • Including image support for SC2000 v6.0 image data.
Secondary Predicate Device Name	**510(k) Number / Clearance Date**	**Substantial Equivalence claimed to: sUSAS support clinical image review and post processing using the same CAPS.**
ACUSON SC2000 Diagnostic Ultrasound System (v5.1) – VB21A *Reference Predicate*	K200585 / 04/22/2020 / IYO	*ACUSON SC2000 Diagnostic Ultrasound system* image display, manipulation, post-processing with Clinical Applications Packages (CAPS) • Volume Review • eSie LVA • eSie PISA • eSie Valves
Reference Predicate Devices	**510(k) Number / Clearance Date**	**sUSAS supports clinical image review and post processing using the same CAPS.**

Syngo® Dynamics PAC System, VA30A	K171053 / June 1, 2017 / LLZ	*Syngo* Dynamics PAC System, VA30A and earlier PACS versions supports the sUSAS Plug-in and launches the clinical applications packages (CAPS) contained in the sUSAS application.

Part 4. Device Description

syngo® Ultrasound Apps Suite™ (sUSAS) is a dedicated software application for use activated on a workstation connected to a cardiology PACS that includes a third-party application launcher. It is a graphical launch pad designed to provide viewing, manipulation and quantification functionality for ACUSON SC2000™ Ultrasound System image data sets using Clinical Application Packages (CAPS).

The analysis packages included in this release of the *syngo*® Ultrasound Apps Suite (formerly eSie Apps Suite) software are essentially the same as those available in the software on the ACUSON SC2000™ Ultrasound System**.** Features on sUSAS are limited to the eSie Volume Viewer (for 2D image and 3D volume image display), eSie LVA, eSie PISA, and eSie Valves clinical application software.

Part 5. Intended Use and Indications for Use Statement

The *syngo*® Ultrasound Apps Suite software is a software-only product to be run on a user's PACS (Picture Archiving and Communication System) workstation. It is intended to launch Siemens CAPs (Clinical Application Packages) for image processing, including the acceptance, transfer, display and digital processing of ultrasound images. Digital processing includes image manipulation and quantification on a workstation. Use of a clinical application package by a qualified clinician can add information to the study to be used for a clinical diagnosis.
The software supports the following clinical application packages:

- eSie Volume Viewer
- eSie LVA
- eSie PISA
- eSie Valves

The indications for use for *syngo*® Ultrasound Apps Suite™ (sUSAS), VA17A remains unchanged from the primary predicate device eSie Apps Suite currently cleared in K143254 except for the device name.

Part 6. Technological Characteristics as compared to Predicate Device

The subject device*: syngo*® Ultrasound Apps Suite ™ (sUSAS) is substantially equivalent to the cleared primary predicate device, eSie Apps Suite (K143254) that employs the same fundamental scientific technology and intended use/indications for use.

The clinical applications packages (CAPS) are the same version as used on the currently cleared SC2000 Diagnostic Ultrasound system v6.0 cleared under K200585 to ensure consistent functionality between the SC2000 Diagnostic Ultrasound system and the sUSAS software plug-in applications. Therefore, the SC2000 v6.0 K200585 is a secondary predicate as v6.0 contains the same CAPS as sUSAS VA17A and *syngo*® Dynamics PACs K171053 will be used as a reference predicate since the sUSAS application is installed as a plug-in and will be included in the comparison table.

A comparison table as Table 2 is provided on the following page:

Table 1: List of Technological Characteristics and SE Comparison Table			
Feature / Characteristic	**eSie Apps Suite K143254 (Predicate device)**	**ACUSON SC2000 Ultrasound System K200585 (Secondary Predicate) Syngo Dynamics K171053 (Reference Predicate)**	***syngo*® Ultrasound Apps Suite™ (sUSAS) (this submission)**
Device Classification (Device class/Product code & panel/description)	Class II LLZ & Radiology Picture archiving and Communications system	Class II IYN, IYO, ITX, OBJ Ultrasonic pulsed doppler imaging system – and - Class II LLZ - PACS	Class II LLZ & Radiology Picture archiving and Communications system
Intended Use/Indication for Use statement	eSie Apps Suite software is a software-only product to be run on a user's PACS (Picture Archiving and Communication System) workstation. It is intended to launch Siemens CAPs (Clinical Application Packages) for image processing, including the acceptance, transfer, display and digital processing of ultrasound images. Digital processing includes image manipulation and quantification on a workstation. Use of a clinical application package by a qualified clinician can add information to the study to be used for a clinical diagnosis. The software supports the following clinical application packages: • eSie Volume Viewer • eSie LVA • eSie PISA • eSie Valves	See clearance letter for K200585 in Attachment B2a. See reference device clearance letter for K171053 in Attachment B3.	*syngo*® Ultrasound Apps Suite software is a software-only product to be run on a user's PACS (Picture Archiving and Communication System) workstation. It is intended to launch Siemens CAPs (Clinical Application Packages) for image processing, including the acceptance, transfer, display and digital processing of ultrasound images. Digital processing includes image manipulation and quantification on a workstation. Use of a clinical application package by a qualified clinician can add information to the study to be used for a clinical diagnosis. The software supports the following clinical application packages: • eSie Volume Viewer • eSie LVA • eSie PISA • eSie Valves SAME AS PREDICATE
Features: Display Measurements and Calculation Packages			

▪ Viewing and manipulation of volume datasets	YES -(eSie volume viewer)	Yes - SC2000 6.0 and lower --- Yes - *syngo* Dynamics via sUSAS installed	SAME - (eSie volume viewer)
▪ 2D quantitative tool for assessment of global and regional myocardial mechanics	No	Yes SC2000 only (eSie VVI) --- No - *syngo* Dynamics via sUSAS installed	No
▪ 3D Left Ventricle volume quantitative analyses (Single + Multibeat)	YES (eSie LVA)	Yes - SC2000 (eSie LVA) +5 beats --- No - *syngo* Dynamics via sUSAS installed	YES (eSie LVA) + 5 beats Update to number of cardiac cycles supported from 3 to 5 beats, SAME As SC2000 6.0
▪ Quantification of proximal isovelocity surface area	YES (eSie PISA) 2D data acquired with TTE probe	Yes - SC2000 (eSie PISA) 2D and 3D volume date acquired with TTE, TEE and ICE probes. Color Doppler & B mode. --- No- *syngo* Dynamics via sUSAS installed	YES (eSie PISA) 2D and 3D volume date acquired with TTE, and TEE probes. Color Doppler only.
▪ 2D Automated tool to identify and measure contours of left ventricle and atrium from transthoracic exams (TTE)	No	Yes - SC2000 (eSie Left Heart) --- No- *syngo* Dynamics via sUSAS installed	No
▪ Visualize and quantify mitral and aortic valve anatomy	YES (eSie Valves)	Yes - SC2000 (eSie Valves) --- No - *syngo* Dynamics via sUSAS installed	YES (eSie Valves) Same as SC2000 6.0 with defect corrections
▪ GUDID Compliance	Yes VA16A	Yes - SC2000 --- Yes - *syngo* Dynamics	YES VA16A
▪ Volume Load Performance	80 secs	N/A for SC2000 ---	40 secs SAME AS VA16A

(Volume load time in volume review)		40 sec on *syngo* Dynamics via sUSAS VA16A installed	
▪ Support SC2000 datasets compatibility	Yes - VA16A – v5.0 VA16B – v5.1	Yes - *syngo* Dynamics VA30A and earlier via sUSAS installed.	Yes, SC2000 6.0 clearance (K200585)
▪ eSie PISA and TTE (only support with TTE Color Doppler volume data)	YES VA16A	Yes for SC2000 5.0 and higher. --- Yes, supported on *syngo* Dynamics imaging via sUSAS VA16A	YES (eSie PISA) Supports TTE Color Doppler Volume same as VA16A
▪ *Syngo* Dynamics (sUSAS support for SC2000 5.1 data)	YES SyDx VA10	Yes - *syngo* Dynamics With sUSAS VA16B	YES SyDx VA20
▪ *Syngo* Dynamics (sUSAS support for SC2000 6.0 data)	YES SyDx VA10	Yes - *syngo* Dynamics With sUSAS VA17A	YES SyDx VA20
▪ Windows 10 Support	No	Yes - SC2000 6.0 --- Yes - *syngo* Dynamics via sUSAS installed	YES (New) for VA17A SAME as SC2000 6.0
▪ DICOM Media Storage Service	YES	Yes - SC2000 6.0 and lower --- Yes - *syngo* Dynamics via sUSAS installed	YES - SAME
▪ DICOM Structed Reporting	YES	Yes - SC2000 6.0 and lower --- Yes - *syngo* Dynamics via sUSAS installed	√ YES - SAME
▪ Display Improvements	No	SC2000 v6.0 - Yes	Yes aligns with SC2000 6.0
VR Measurement Tools ▪ (Volume)	No	SC2000 v6.0 - Yes	The ability to measure anatomy and pathology directly on the Volume Rendered (VR) images in CINE and acquired in 4D. Same as on SC2000 6.0
Reference Lines One-click MPR alignment ▪	No	SC2000 v6.0 - Yes	New Display Feature Same as on SC2000 6.0

Volume Reference Line Projections eSie Slice / eSie Lines ▪	No	SC2000 v6.0 - Yes	New Display Feature Same as on SC2000 6.0
▪ One-click MPR A/B Align on Volume Review (VR)	No	SC2000 v6.0 - Yes	New Display Feature Same as on SC2000 6.0
▪ Trace erase, back up behavior with Trackball: B-Mode	No	SC2000 v6.0 - Yes	Updated Display Feature Same as on SC2000 6.0
▪ D'Art renamed Single V	No	SC2000 v6.0 - Yes	YES - Consolidated windows Same as on SC2000 6.0

Substantial Equivalence Conclusion:

From the information provided in Table 2 above; it is understood that the subject device does not introduce any new fundamental technology or modify the indications of use; therefore, sUSAS VA17A is considered substantially equivalent to the predicate device; the eSie Apps Suite VA15A cleared in K143254 utilizing the same Clinical Applications (CAPS) as cleared on the Secondary predicate ACUSON SC2000 Diagnostic Ultrasound System v6.0 (K20085) The sUSAS VA17A is intended to be a plug-in on a PACS such as the the reference predicate syngo® Dynamics PACS workstation (K171053) or earlier versions.

Part 7. A brief discussion of nonclinical testing submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

syngo® Ultrasound Apps Suite™ (sUSAS) is verified, and validated according to the design control requirements of 21 CFR 820.30 and has been subjected to extensive safety and requirements verification testing before release to ensure the device meets all its specifications including conformance to the following standards:

- IEC 62304:2006/A1:2016 Medical Device Software – Software Life Cycle Processes
- IEC 62366-1:2015, Application of usability engineering to medical devices.
- NEMA PS 3.1 – 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM set).

The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

Software Verification and Validation

In accordance with the FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, documentation is included within this submission for software of a Moderate Level of Concern. Non-clinical Testing was conducted during product development. Evidence provided within this submission demonstrates conformance with special controls for medical devices containing software.

Cybersecurity considerations related to the sUSAS software only plug-in is included within this submission. Siemens 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.

A risk analysis, in compliance with ISO 14971:2007, for sUSAS was conducted and mitigation controls were implemented for identified hazards. Verification and validation testing confirm that all software specifications have been implemented and met the defined acceptance criteria. Further, documentation is provided to support the claim of substantial equivalence.

Part 8. A summary discussion of the clinical tests submitted, referenced, or relied on for a determination of substantial equivalence.

syngo® Ultrasound Apps Suite™ (sUSAS) is a class II device and uses the same technology and operating principles as the predicate device; eSie Apps Suite (K143254), therefore clinical studies were not required to support substantial equivalence.

Part 9. Safety and Effectiveness Information

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 into 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 believes that *syngo*® Ultrasound Apps Suite, version VA17A is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

Part 10. Conclusion as to Substantial Equivalence Summary

Based on the information provided here in the summary and from the device comparison in Table 2; the *syngo*® Ultrasound Apps Suite™ (sUSAS); VA17A has the same indications for use as the primary predicate device (K143254) (except new product name); incorporates technological features

of the primary predicate device and the same Clinical Applications Packages (CAPS) as the primary predicate (K143254) and as the secondary predicate device (K200585) cleared through premarket notification and performance testing which indicates that no new issues of safety or effectiveness are raised.

Siemens Medical Solutions USA, Inc, Ultrasound Business Unit. considers the *syngo*® Ultrasound Apps Suite™ (sUSAS) VA17A to be substantially equivalent with respect to safety and effectiveness to the previously cleared predicate device for the U.S. market.