DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Healthcare GmbH
℅ Mr. Olaf Teichert
Third Party Reviewer
TUV SUD America Inc.
1775 Old Hwy 8 NW, Suite 104
NEW BRIGHTON MN 55112

June 1, 2017

Re: K171053
    Trade/Device Name: syngo® Dynamics Version VA30
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: II
    Product Code: LLZ
    Dated: May 18, 2017
    Received: May 25, 2017

Dear Mr. Teichert:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
  and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
k171053

Device Name
syngo Dynamics Version VA30

Indications for Use *(Describe)*

syngo Dynamics is an image and information system intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including review, analysis, quantification and reporting.

As a Cardiology PACS and information system, syngo Dynamics supports the physician in interpretation and evaluation of examinations within healthcare institutions, in particular, in Cardiology, Obstetrics and Gynecology or other departments.

syngo Dynamics is not intended to be used for displaying of digital mammography images for diagnosis 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.

510(k) Summary

syngo® Dynamics (Version VA30)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Date prepared: March 27, 2017

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3. **Device Name and Classification**

Trade Name:	*syngo*® Dynamics Version VA30
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

4. **Legally Marketed Predicate Device**

Trade Name:	*syngo* Dynamics
510(k) Clearance:	K123922

Clearance Date:	January 16, 2013
Classification Name:	Picture Archiving and Communication System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

5. Device Description

This premarket submission notification addresses the Siemens *syngo*® Dynamics Version VA30 Picture Archiving and Communication System.

syngo Dynamics VA30, is a digital image display and reporting system. This system can function as a standalone medical device that includes a DICOM server or as an integrated module within and 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 syngo Dynamics system provides components that can be used to review, edit and manipulate image data, as well as to generate quantitative data, qualitative date and diagnostic reports. *syngo* Dynamics VA30 also provides advanced reporting support for cardiology, OB/GYN, MFM (maternal fetal medicine) and vascular ultrasound studies.

syngo Dynamics is a software only medical device. Recommended configurations are defined for the hardware required to run the device. The hardware itself is not seen as a medical device and not in the scope of this 510(k) submission.

syngo Dynamics is based on a client-server architecture. The server processes the data from the connected imaging modalities. The client provides the user interface for interactive image viewing and processing and can be installed on remote, network connected, workstation machines or through industry standard virtualization software.

Since the majority of the data processing is performed by the server, the client can be installed on standard off-the-shelf computers with a variety of monitor types. The quality of displayed images highly depends on the quality and settings of monitors, graphics cards, and graphics drivers. It is the customer's responsibility that client monitors are compatible with graphics cards and graphics drivers. It is also the customer's responsibility to use suitable monitors for diagnostic purposes.

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.

syngo® Dynamics VA30 and its predicate device have the same fundamental technical characteristics.

6. Intended Use

syngo Dynamics is an image and information system intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including review, analysis, quantification and reporting.

As a Cardiology PACS and information system, syngo Dynamics supports the physician in interpretation and evaluation of examinations within healthcare institutions, in particular, in Cardiology, Obstetrics and Gynecology or other departments.

syngo Dynamics is not intended to be used for displaying of digital mammography images for diagnosis in the U.S.

7. Summary of Differences Between the Subject Device and the Predicate Device

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

	Subject Device *syngo* Dynamics VA30	Predicate Device *syngo* Dynamics VA10A
Manufacturer	Siemens Healthcare GmbH	Siemens Medical Solutions USA, Inc.
Software Architecture	Client-server architecture	Client-server architecture
Operating System	Server Windows 2012 R2 Server Standard Edition R2 (64-bit) Portal Client Windows 7 SP1 or higher 64-bit Portal Website Host Windows 2012 R2 Server Standard Edition R2 (64-bit)	Server Windows 2008 R2 Server Standard Edition R2 SP1 or SP2 (64-bit) Workplace Microsoft Windows 7 or Windows 7 SP1 or higher · 32-bit or 64-bit · Ultimate, Professional, Enterprise, Ultimate N, Professional N, or Enterprise N Portal Website Host Windows Server 2008 R1 32-bit or greater
Image Source	DICOM Ultrasound, XA, DX, DR and Nuclear Medicine, including PET.	DICOM Ultrasound, XA, DX, DR and Nuclear Medicine, including PET.
Image Display	Ultrasound, XA, DX, DR, PET and Nuclear Medicine through Corridor4DM	Ultrasound, XA, MR, DX, DR, PET and Nuclear Medicine through Corridor4DM
Data Export	DICOM, bmp, avi	DICOM, bmp, avi
Image Communication	Within the network, the following communication protocols are used: · TCP/IP: for communication and transport · DICOM and HL7 at	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 thumbnails	application level · HTTP for communication and transport of thumbnails
Image Data Compression	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate.	Lossless compression with compression factor 2 to 3 and lossy compression with higher compression rate.
Imaging Algorithms	Window/Leveling, Edge Enhancement, and Digital Subtraction	Window/Leveling, Edge Enhancement, and Digital Subtraction
Quantitative Algorithms	Pixel Size Evaluation	Pixel Size Evaluation
Network Access	Yes	Yes
Analysis	Yes	Yes
Reporting	Yes	Yes
Decision Support Interface to Rules Engine	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 provides a trigger to pull in previously stored relevant data for a given study.	n/a
Send Critical Results	End user, identified critical Results are sent to the EHR quickly	n/a
Multimodality storage and review	Yes	Yes
Web Server for images and clips	Yes	Yes
Report upload to Information Systems	Yes, through broker or interface engine	Yes, through broker or interface engine
DICOM Structured Reporting	Yes	Yes
Export/Import Data Sets via removable media or network means	n/a	Yes
Vascular Quantification	Yes, measurements and calculations	Yes, measurements and calculations
Data Mining	Yes	Yes
Discrete Data Export	Yes	Yes
Cardiac Measurements	Yes	Yes
Interactive graphical documentation for reporting	Coronary Tree Diagrams are the same in VA30. Congenital Heart Diagrams and Vascular Diagrams have been added in the Common Reporting Component.	Coronary Tree Diagrams

Hemodynamic data import (third party vendor)	Yes	Yes
Web Reporting	Yes	Yes
Electronic Health Record (EHR) Interfacing	Basic report and discrete data upload to EHR. Ability to integrate DICOM Image Review and Common Reporting Component with Cerner Electronic Health Record System and PACS.	Basic report and discrete data upload to EHR
Collaborative Reporting	Yes	Yes
Mobile Device Support	Images can be viewed on mobile devices, but are still non-diagnostic.	Yes – Non-diagnostic, and read-only. Support Apple iPhone and iPad.

8. Clinical Testing

No clinical studies were carried out for syngo Dynamics VA30. All performance testing was conducted in a non-clinical fashion as part of the verification and validation activities for the medical device.

9. Non-Clinical Performance Testing

Non-clinical testing was conducted for the device *syngo* Dynamics during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.
Siemens claims conformance to the following standards:

- NEMA PS3 Digital Imaging and Communications in Medicine (DICOM)
- ISO 14971:2007
- ANSI/AAMI ES 60601-1, A1, clauses 14.11 and 14.13
- IEC 62304: 2006
- IEC 62366-1:2015
- IEC 10918-1:1994 + Technical Corrigendum 1:2005
- ISO/HL7 21731:2014

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 *syngo* Dynamics are 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 *syngo* Dyanamics was conducted and mitigation controls were implemented for identified hazards. Verification and validation testing confirms that all software specifications have been implemented and met the defined acceptance criteria. Further, documentation is provided to support the claim of substantial equivalence.

10. 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* Dynamics version VA30 is safe and effective as the identified predicate device and does not introduce new safety and effectiveness concerns.

11. Conclusion as to Substantial Equivalence

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 is of the opinion that *syngo* Dynamics version VA30 does not introduce any new significant potential safety risks and is substantially equivalent to the predicate device.