DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2017

Siemens Medical Solutions USA, Inc.
Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd., Mail Code 65-1 A
Malvern, Pennsylvania 19355

Re: K170952
Trade/Device Name: syngo.CT View&GO
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 21, 2017
Received: March 31, 2017

Dear Ms. Kimberly Mangum:

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,

For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170952

Device Name

syngo.CT View&GO

Indications for Use *(Describe)*

syngo.CT View&GO is intended for basic visualization of medical images that are used for diagnostic purposes. The software package is designed to support trained technicians and trained physicians in basic qualitative and basic quantitative measurements as well as in the analysis of clinical data that has been acquired and reconstructed on Computed Tomography scanners. The software package shall also provide the possibility to save image data and to trigger the transfer of image data to other systems, such as printers or archiving systems. The software package shall provide an interface to integrate additional advanced visualization and measurement tools.

Basic visualization of medical images includes, for example:
• Adjusting of windowing level presets
• Zooming and panning of images
• Multiplanar reconstruction (MPR) display
• Maximum intensity projection (MIP) display
• Volume rendering techniques (VRT) display

Basic qualitative and basic quantitative measurements include, for example:
• Distance measurements
• Region of interest (ROI) measurements
• Pixel lens to measure local HU values

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.

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510(K) SUMMARY
FOR
SYNGO.CT VIEW&GO

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

Date Prepared: March 21, 2017

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.

I. Submitter

Importer/Distributor
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Establishment Registration Number
2240869

Manufacturing Site
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Establishment Registration Number
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II. Device Name and Classification

Product Name:	syngo.CT View&GO
Proprietary Name:	syngo.CT View&GO
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
Secondary Classification Name:	Computed Tomography X-ray System
Secondary Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Secondary CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	LLZ
Secondary Product Code:	90JAK

III. Predicate Device

Primary Predicate Device:
Trade Name: syngo®.via (version VB10A)

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510(k) Number:	K150843
Clearance Date:	04/24/2015
Classification Name:	Picture archiving and communications system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ
Recall Information:	There are currently no recalls for this device

Reference Device:

Trade Name:	Fly Through
510(k) Number:	K971717
Clearance Date:	09/03/1997
Classification Name:	System, x-ray, tomography, computed
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

IV. Device Description

The application syngo.CT View&GO is intended for basic visualization of medical images that are used for diagnostic purposes. It is designed to support trained technicians and trained physicians in basic qualitative and basic quantitative measurements as well as in the analysis of clinical data that has been acquired and reconstructed on Computed Tomography scanners. The application also provides the possibility to save image data and to trigger the transfer of image data to other systems, such as printers or archiving systems. In addition, syngo.CT View&GO provides an interface to integrate additional advanced post processing tools through the plug-in functionality of syngo.CT View&GO.

The application provides the basic visualization features (for example):

- Adjusting of windowing level presets
- Zooming and panning of images
- Multiplanar reconstruction (MPR) display
- Maximum intensity projection (MIP) display
- Volume rendering techniques (VRT) display

Furthermore, basic qualitative and quantitative measurements are supported (for example):

- Distance measurements
- Region of interest (ROI) measurements
- Pixel lens to measure local HU values

syngo.CT View&GO also provides an interface to extend this application for additional advanced post processing tools through the plug-in functionality of syngo.CT View&GO.

This subject device contains the following modifications/improvements in comparison to the predicate device syngo®.via (version VB10A):

1) New marketing name: syngo.CT View&GO
2) Modified Indications for Use Statement
3) Software version SOMARIS/8 VB20A which supports for following:
    - Extensibility (modified)
    - Visualization tools (improved)
    - Workflow and arrangement of commonly utilized tools (improved)
    - Distribution of images in DICOM node (improved)

The subject device syngo.CT View&GO is designed to operate on a syngo compatible host system (e.g. syngo.via VB20 software platform or higher). A comparison of these modifications with respect to the predicate device is provided in the “Comparison pf Technological Characteristics with the Predicate Device” section below.

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V. Indications for Use

syngo.CT View&GO is intended for basic visualization of medical images that are used for diagnostic purposes. The software package is designed to support trained technicians and trained physicians in basic qualitative and basic quantitative measurements as well as in the analysis of clinical data that has been acquired and reconstructed on Computed Tomography scanners. The software package shall also provide the possibility to save image data and to trigger the transfer of image data to other systems, such as printers or archiving systems. The software package shall provide an interface to integrate additional advanced visualization and measurement tools.

Basic visualization of medical images includes, for example:

- Adjusting of windowing level presets
- Zooming and panning of images
- Multiplanar reconstruction (MPR) display
- Maximum intensity projection (MIP) display
- Volume rendering techniques (VRT) display

Basic qualitative and basic quantitative measurements include, for example:

- Distance measurements
- Region of interest (ROI) measurements
- Pixel lens to measure local HU values

VI. Comparison of Technological Characteristics with the Predicate Device

Both the subject and predicate device have the same Intended Use, similar Indications for Use and the same visualization and measurement technological features. The minor differences between the subject and the predicate device are as follows:

- The Shaded Surface Display visualization feature has been improved by providing the possibility to fly through any hollow or tubular anatomical structures. This technology is not new and has been cleared with K971717 which is used as a reference device;
- The subject device includes workflow improvements (Tool Box / Favorite Tools and Distribution Step) to provide a faster access the tools of syngo.CT View&GO.

At a high-level, the subject and predicate device are based on the following same/similar technological characteristics:

Feature	Subject Device	Predicate Device (K150843)	Comparison Results
Software	SOMARIS/8 VB20A	SOMARIS/8 VB10A	Subject device supports a new version of SOMARIS/8 software.
Extensibility	Extendable via additional post-processing tools	Extendable via additional post-processing applications	The subject device supports additional post processing tools that can be accessed via plug-in functionality
Visualization Tools	Standard visualization tools in conjunction with Endoscopic View support visualization inside hollow or tubular anatomical structures (such as airways and intestines)	Standard visualization tools in conjunction with Shaded Surface Display	The subject device has been modified to support endoscopic visualization inside hollow tubular anatomical structures.
Measurement and Annotation Tools	Standard measurement tools (e. g. distance line)	Standard measurement tools (e. g. distance line)	Same
Image Creation	Standard image creation tools (e. g. radial ranges)	Standard image creation tools (e. g. radial ranges)	Same
Printing	Basic printing functionality	Basic printing functionality	Same

Feature	Subject Device	Predicate Device (K150843)	Comparison Results
Image Distribution and Archiving	In the Distribution step it is shown to which DICOM nodes a series will be sent when saving the case, or to which node a series has already been sent. The user can select (or deselect) whether a series will be sent to any DICOM node or to a subset of nodes.	Sending of DICOM data to DICOM nodes possible in the export functionality	The subject device has been modified to support transfer of a series of data to any DICOM node or a subset of nodes.
Tool Organization	Functions are organized in the Tool Area and Favorite Tools.	Functions are organized in corner menus and common control area.	The subject device measurement and visualization functions are organized for easier user access.
User Interface	syngo.via GUI	syngo.via GUI	Same
Archiving/Storing	CD-R, film, DVD, USB, Network	CD-R, film, DVD, USB, Network	Same
Communication	DICOM compatible	DICOM compatible	Same

The subject device syngo.CT View&GO does not have significant changes in technological characteristics when compared to the predicate device. Any differences in technological characteristics do not raise different questions of safety and effectiveness. Overall, the subject device post-processing software functionality remains unchanged from the predicate device. The operating principle and the scientific technology are same. Testing and validation is completed. Test results show that the subject device, syngo.CT View&GO, is comparable to the predicate device in terms of technological characteristics and safety and effectiveness, therefore Siemens believes the subject device is substantially equivalent to the predicate device.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination. This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted for syngo.CT View&GO during product development. The modifications described in this Premarket Notification were supported with verification/validation testing. Verification and Validation testing for the endoscopic view feature was conducted to demonstrate successful software integration and performance in accordance to Siemens internal procedure which includes risk identification and mitigation in accordance with ISO 14971. All verification and validation testing has been completed and meets Siemens acceptance criteria. Additionally, all risks for the complete subject device have been identified and mitigated in accordingly.

Risk Analysis

The risk analysis was completed and risk control 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.

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 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing supports that all software specifications have met the acceptance criteria. Verification and validation testing supports the claims of substantial equivalence.

Siemens Healthcare 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. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity Medical Devices issues on October 2, 2014" is included within this submission.

Non-Clinical Testing Summary
Performance tests were conducted to test the functionality of the syngo.CT View&GO. These tests have been performed to test the ability of the included features of the subject device. The results of these tests demonstrate that the subject device performs as intended. The result of all conducted testing was found acceptable to support the claim of substantial equivalence.

Recognition Number	Product Area	Title of Standard	Publication Date	Standards Development Organization
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 – 3.20	06/27/2016	NEMA
13-32	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)	08/20/2012	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	08/20/2012	ISO
5-95	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	06/27/2016	IEC
19-4	General II (ES/EMC)	AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod)	07/09/2014	AAMI, ANSI

General Safety and Effectiveness Concerns
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device. Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing according to the Risk Management process. syngo.CT View&GO is designed to fulfill recognized and established industry practice and standards.

Summary
The features described in this premarket notification are supported with verification and validation testing during product development. The risk analysis was completed and risk control implemented to mitigate identified hazards. The test results show that all of the software specifications have met the acceptance criteria. Verification and validation testing of the device was found acceptable to support the claim of substantial equivalence.

VIII. Conclusions

syngo.CT View&GO has the same intended use and a similar indication for use as the predicate device. The technological characteristics such as image visualization, operating platform, and image manipulation remain unchanged from the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. The predicate device was cleared based on non-clinical supportive information and clinical images. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The comparison of technological characteristics, non-clinical performance data, and software validation 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. For the subject device, syngo.CT View&GO, Siemens used the same testing with the same workflows as used to clear the predicate device. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.CT View&GO testing supports a finding of substantial equivalence.