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

August 13, 2015

Siemens Medical Solutions USA, Inc.
% Ms. Eve Davis
Regulatory Affairs Specialist
51 Valley Stream Parkway
MALVERN PA 19355

Re: K151380
Trade/Device Name: syngo.via RT Image Suite
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ and LLZ
Dated: May 21, 2015
Received: May 22, 2015

Dear Ms. Davis:

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.
Acting 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)*
K151380

Device Name
syngo.via RT Image Suite

Indications for Use *(Describe)*

syngo.via RT Image Suite is a 3D and 4D image visualization, multimodality manipulation and contouring tool that helps the preparation and response assessment of treatments such as, but not limited to those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy).

It provides tools to efficiently view existing contours, create, edit, modify, copy contours of regions of the body, such as but not limited to, skin outline, targets and organs-at-risk. Contours and images can subsequently be exported to a Treatment Planning System. The software combines following digital image processing and visualization tools:

- Multi-modality viewing and contouring of anatomical, functional, and multi-parametric images such as but not limited to CT, PET, PET/CT, MRI, and Linac Cone Beam CT (CBCT) images
- Multiplanar reconstruction (MPR) thin/thick, minimum intensity projection (MIP), volume rendering technique (VRT)
- Freehand and semi-automatic contouring of regions-of-interest on any orientation including oblique
- Creation of contours on any type of images without prior assignment of a planning CT
- Manual and semi-automatic registration using rigid and deformable registration
- Supports the user in comparing, contouring, and adapting contours based on datasets acquired with different imaging modalities and at different time points Supports the user in comparing images and contours of different patients
- Supports multi-modality image fusion
- Visualization and contouring of moving tumors and organs

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.via RT Image Suite

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: May 21, 2015

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.

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
Siemens AG
Medical Solutions
Siemens Str. 1
D-91301 Forchheim, Germany

Establishment Registration Number:
3004977335

2. Contact Person:

Eve Davis
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway, Mail Code D02
Malvern, PA 19355
Phone: (610) 219-7133
Fax: (610) 448-1787
Email: eve.davis@siemens.com

3. Device Name and Classification

Product Name:	*syngo*.via RT Image Suite
Propriety Trade Name:	*syngo*.via RT Image Suite
Classification Name:	system, planning, radiation therapy treatment
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	MUJ
Additional Product Code:	LLZ

Legally Marketed Primary Predicate Device:

Trade Name:	*syngo*® Dosimetrist Workspace v2.7
510(k)#:	K101119
Clearance Date:	June 16, 2010
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.5050
Device Class:	II
Product Code:	MUJ
Recall Information:	Recall 68395

Legally Marketed Secondary Predicate Device:

Trade Name:	syngo.PET&CT Oncology
510(k)#:	K093621
Clearance Date:	February 23, 2010
Classification Name:	Picture Archiving and Communication Systems
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.2050
Device Class:	II
Product Code:	LLZ
Recall Information:	There have been no recalls for this device

4. Substantial Equivalence:

The subject device, *syngo*.via RT Image Suite, is substantially equivalent to following medical devices in commercial distribution:

Predicate Devices	***FDA Clearance Number***	***FDA Clearance Date***
Primary Predicate Device: Siemens *syngo*® Dosimetrist Workspace v2.7	K101119	June 16, 2010
Secondary Predicate Device: Siemens *syngo*.PET&CT Oncology	K093621	February 23, 2010

5. Device Description:

syngo.via RT Image Suite is an image analysis software used for viewing, manipulation, 3D and 4D visualization, comparison of medical images from multiple imaging modalities and for the segmentation of tumors and organs-at-risk, prior to dosimetric planning and response assessment in radiation therapy. syngo.via RT Image Suite combines routine and advanced digital image processing and visualization tools for easy manual and software assisted contouring of volumes of interest, identification of points of interest, registering images and exporting final results.

syngo.via RT Image Suite supports the medical professional with tools to use during different steps in radiation therapy case preparation.

The *syngo*.via RT Image Suite post-processing software application is embedded in the Siemens *syngo*.via framework (operating platform most recently cleared as VB10 K150843) of a multi-user HW/SW architecture with Client-Server support. Software information is located in **Section 16**.

The following modifications have been made to the previously cleared primary predicate device (*syngo*® Dosimetrist Workspace 2.7 K101119, clearance date June 16 2010) and the secondary predicate device (syngo.PET&CT Oncology K093621, clearance date February 23 2010).

1. A new software version SOMARIS/8 VB10 which supports the following:
    - New post-processing software application “syngo.via RT Image Suite” which has been designed for the new syngo.via platform (SOMARIS/8 VB10) and contains the following application modifications compared to the predicate devices:
        - Advanced Contouring: offers freehand editing and 3D Nudge tools for editing in non-original image orientations. These two features are segmentation improvements to the already cleared feature “Advanced Segmentation” described in Premarket Notification K101119, clearance date 06/16/2010.
        - Deformable Alignment: for cases where rigid alignment does not provide sufficient anatomical correspondence between secondary images and the reference image, deformable registration is an option. The deformable registration allows the user to map the corresponding anatomy captured in the two images. Rigid Alignment has been cleared within the Premarket Notification K093621, cleared date 02/23/2010.
        - Contouring on 4D CT: The subject device allows the user to display a cine loop of images acquired through gated CT. This is a new feature supported by software testing.
2. An extended, more descriptive Indication for Use statement to include details of device functionality

6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

syngo.via RT Image Suite has the same intended use and operating principle as the predicate devices. The *syngo*.via RT Image Suite application is designed to be operated on the *syngo*.via platform in a single or multi server environment.

syngo.via RT Image Suite does not have significant changes in technological characteristics when compared to the predicate devices. The subject device is the same to either one or both of the predicate devices in regards to:

- Visualization
- Routine Contouring
- Annotation
- Reference Point Management
- Structure Set Management
- User Interface
- Archiving/Storage
- Hardware
- Image Processing and Evaluation
- Communication

The following table shows the differences in technological characteristics between the subject device and the predicate devices.

Table 1: Differences in technical characteristics

Feature	***Subject Device*** *syngo.via RT Image Suite*	***Primary Predicate Device*** *Siemens syngo® Dosimetrist Workspace v2.7 (K101119)*	***Secondary Predicate Device*** *Siemens syngo.PET&CT Oncology (K093621)*	***Comparison***
Advanced Contouring	Freehand editing 3D	Random Walker Tools	N/A	The subject device offers freehand 3D editing and 3D Nudge tools for editing in non-original image orientations. These two features are segmentation improvements to the 2D tools cleared in K101119. Contour interpolation was cleared as part of both the primary and secondary predicate devices.
	Nudge 3D	Contour Nudge Tool	N/A	
	Contour interpolation	Contour interpolation	Contour interpolation	
Alignment	Rigid alignment tools	Rigid alignment tools	Rigid alignment tools	The subject device contains the same rigid alignment tools as cleared in both the primary and secondary predicate devices

Feature	***Subject Device*** *syngo.via RT Image Suite*	***Primary Predicate Device*** *Siemens syngo® Dosimetrist Workspace v2.7 (K101119)*	***Secondary Predicate Device*** *Siemens syngo.PET&CT Oncology (K093621)*	***Comparison***
	Deformable alignment tools	N/A	N/A	The Deformable alignment used to map the corresponding anatomy captured on two registered images is an optional, additional feature for cases where rigid alignment does not provide sufficient anatomical correspondence between secondary images and the reference image.
Contouring on 4D CT	Present	N/A	N/A	The subject device allows the user to display a cine loop of images acquired through gated CT. This is a new feature and was not available on the predicate devices.

7. Nonclinical Testing:

syngo.via RT Image Suite is designed to fulfill the requirements of the following safety and performance standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
12-238	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.18	03/16/2012	NEMA
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	08/20/2012	ISO
5-85	General	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability	60601-1-6 Edition 3.0 2010-01	1/30/2014	IEC
5-41	General	Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4:2000, Consol. Ed. 1.1	09/08/2009	IEC

Verification and Validation
This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Integration and functional tests were conducted for syngo.via RT Image Suite during product development.

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 test results show that all of the software specifications have me the acceptance criteria.

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.

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. It is the hospital's responsibility to comply with IEC 8001-1-2010.

Summary
Performance tests were conducted to test the functionality of the subject device, syngo.via RT Image Suite. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

8. Indications for Use:
syngo.via RT Image Suite is a 3D and 4D image visualization, multimodality manipulation and contouring tool that helps the preparation and response assessment of treatments such as, but not limited to those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy).

It provides tools to efficiently view existing contours, create, edit, modify, copy contours of regions of the body, such as but not limited to, skin outline, targets and organs-at-risk. Contours and images can subsequently be exported to a Treatment Planning System. The software combines following digital image processing and visualization tools:

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- Supports multi-modality image fusion
- Visualization and contouring of moving tumors and organs

9. 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. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence

The predicate devices were cleared based on non-clinical supportive information. The subject device was tested using the same non-clinical methods. The subject device non-clinical data supports the safety of the software with verification and validation testing. Verification and Validation testing also demonstrates that syngo.via RT Image Suite performs as intended. The non-clinical test data demonstrates that syngo.via RT Image Suite device performance is comparable to the predicate devices that are currently marketed for the same intended use.
In summary, Siemens is of the opinion that the syngo.via RT Image Suite does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.