



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

Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd., Mail Code 65-1A
MALVERN PA 19355

October 25, 2016

Re: K162370

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, LLZ
Dated: August 12, 2016
Received: August 24, 2016

Dear Ms. 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 yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

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)
K162370

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, Linac Cone Beam CT (CBCT) images and dose distributions
- 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
- Management of points of interest including but not limited to the isocenter

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
FOR
SYNGO.VIA RT IMAGE SUITE**

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

Date Prepared: August 12, 2016

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

Siemens Healthcare GmbH
Siemensstr. 1
D-91301 Forchheim, Germany

Establishment Registration Number

3004977335

Contact Person

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II. 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
Subsequent CFR Section: 21 CFR §892.2050
Device Class: Class II
Product Code: MUJ
Subsequent Product Code: LLZ

III. Predicate Device

Primary Predicate Device:

Trade Name: syngo.via RT Image Suite
510(k) Number: K151380
Clearance Date: August 13, 2015
Classification Name: System, Planning, Radiation Therapy Treatment
Classification Panel: Radiology
CFR Section: 21 CFR §892.5050
Subsequent CFR Section: 21 CFR §892.2050
Device Class: Class II
Product Code: MUJ
Subsequent Product Code: LLZ
Recall: There have been no recalls for this device

Secondary Predicate Device:

Trade Name: syngo Dosimetrist Workspace v2.7
510(k) Number: K101119
Clearance Date: October 9, 2010
Classification Name: System, Planning, Radiation Therapy Treatment
Classification Panel: Radiology
CFR Section: 21 CFR § 892.5050
Device Class: Class II
Product Code: MUJ
Recall: 68395

IV. Device Description

syngo.via RT Image Suite is an image analysis software 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, sending isocenter points to an external laser system, 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.

syngo.via RT Image Suite provides dedicated tools, which help the medical professional in contouring and evaluating volumes of interest, for example gross target volumes, or organs-at-risk.

The software application works in a similar fashion on any officially supported imaging modality, for example, native contouring is supported on CT but also on MR or PET images.

The following features have been modified:

- Routine Annotation Functionality (*modified*)
- Contouring Tools (*modified*)
- Patient Marking (*modified*)
- Structure Set Management (*modified*)

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- Alignment Tools (*modified*)
- Dose Evaluation (*new*)

V. 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:

- Multi-modality viewing and contouring of anatomical, functional, and multi-parametric images such as but not limited to CT, PET, PET/CT, MRI, Linac Cone Beam CT (CBCT) images and dose distributions
- 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
- Management of points of interest including but not limited to the isocenter

VI. Comparison of Technological Characteristics with the Predicate Device

syngo.via RT Image Suite has the same intended use, operating principle as well as the image visualization and manipulation technological characteristics as the predicate devices. Evaluation and post-processing are the technological principles for both the subject and predicate devices. The fundamental features of this subject device are: viewing, manipulation, 3D and 4D visualization, comparison of medical images from multiple imaging modalities and the segmentation of tumors and organs-at-risk, prior to dosimetric planning and response assessment in radiation therapy. The indications for use are similar.

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Using a high-level comparison, the subject and predicate devices are based on the following same technological elements respectively have the following differences:

Table 4 Differences and Similarities in Technical Characteristics

Feature	Subject Device syngo.via RT Image Suite	Primary Predicate Device syngo.via RT Image Suite	Secondary Predicate Device syngo Dosimetrist Workspace v2.7	Comparison
<i>Basic Features</i>	Routine Reading Functionality; Parallel Image Display; Routine Annotation Functionality	Routine Reading Functionality; Parallel Image Display; Routine Annotation Functionality	Routine Reading Functionality; Parallel Image Display	Routine Annotation Functionality supports now a finding feature
<i>Contouring</i>	Routine Contouring; Advanced Contouring; Contouring on 4D Image Data; Routine Structure Operations; Duplication of Structures and POIs	Routine Contouring; Advanced Contouring; Contouring on 4D Image Data; Routine Structure Operations; Duplication of Structures and POIs	Routine Contouring; Advanced Contouring; Routine Structure Operations	Routine & Contouring Tools and Contouring on 4D Image Data have been improved
<i>Patient Marking</i>	Transmission of POIs of type isocenter to an external laser system	n/a	Transmission of POIs of type isocenter to an external laser system	New feature in the subject device but is similar to the secondary one
<i>Alignment Tools</i>	Rigid Alignment and Deformable Alignment	Rigid Alignment and Deformable Alignment	Rigid Alignment	Rigid and Deformable Alignment tools have been improved to provide a better workflow
<i>Dose Evaluation</i>	Loading of any existing dose files; Addition or Subtraction of two dose files	n/a	n/a	new feature

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.via RT Image Suite during product development. The modifications described in this Premarket Notification were supported with verification/validation testing.

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 Major 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.

Non-Clinical Testing Summary

Performance tests were conducted to test the functionality of the syngo.via RT Image Suite. 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.

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

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used to identify potential hazards. These potential hazards are controlled during development, verification and validation 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
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20	06/27/2016	NEMA
N/A	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	06/27/2016	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	07/09/2014	IEC
N/A	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

In this subject device six scientific articles are used to support the marketing claims provided in the product brochure.

VIII. Conclusions

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. Furthermore, for the subject device, syngo.via RT Image Suite, Siemens used the same testing with the same workflows as was used to clear the predicate devices. Since both devices were tested using the same methods, Siemens believes that the data generated from the syngo.via RT Image Suite testing supports a finding of substantial equivalence.

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.