Siemens Medical Solutions USA, Inc.
% Ms. Cynthia Busch
Regulatory Affairs Specialist
2501 N Barrington Road
HOFFMAN ESTATE IL 60192

August 13, 2020

Re: K201444
Trade/Device Name: syngo.via RT Image Suite
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: May 29, 2020
Received: June 1, 2020

Dear Ms. Busch:

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)*
K201444

Device Name
syngo.via RT Image Suite

Indications for Use *(Describe)*

syngo.via RT Image Suite is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation 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 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. It also provides functionalities to create simple geometric treatment plans. Contours, images and treatment plans can subsequently be exported to a Treatment Planning System.

The software combines the 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 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
- Automated Contouring on CT images
- Creation of contours on images supported by the application 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 multi-modality image fusion
- Visualization and contouring of moving tumors and organs
- Management of points of interest including but not limited to the isocenter
- Creation of simple geometric treatment plans
- Generation of a synthetic CT based on multiple pre-define MR acquisitions

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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K201444

Section 5

510(k) Summary

I. Identification of the Submitter

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

Establishment Registration Number 2240869

Manufacturing Site
Siemens Healthcare GmbH
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D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Submitter Contact Person:
Cynthia Busch
Regulatory Affairs Specialist
2501 North Barrington Road
Hoffman Estates, IL 60192-2061
Phone: (847) 643-6818 Email: cynthia.busch@siemens-healthineers.com

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
Device Class:	Class II
Product Code:	MUJ

III. Predicate Device

Trade Name:	syngo.via RT Image Suite
510(k) Number:	K192065
Clearance Date:	09/18/2019
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Panel:	Radiology
CFR Section:	21 CFR §892. 5050
Device Class:	Class II
Product Code:	MUJ

IV. Device Description

The subject device with the current software version SOMARIS/8 VB50 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 in radiation therapy. syngo.via RT Image Suite combines routine and advanced digital image processing and visualization tools for 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.

The following already cleared features in the previous version of syngo.via RT Image Suite (SOMARIS/8 VB40) have been modified:

- Contouring
  - Routine Contouring
  - Advanced Contouring
- Structure Set Management
- Deformable Alignment

V. Indications for Use

syngo.via RT Image Suite is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation 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 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. It also provides functionalities to create simple geometric treatment plans. Contours, images and treatment plans can subsequently be exported to a Treatment Planning System.

The software combines the 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

- 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
- Automated Contouring on CT images
- Creation of contours on images supported by the application 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 multi-modality image fusion
- Visualization and contouring of moving tumors and organs
- Management of points of interest including but not limited to the isocenter
- Creation of simple geometric treatment plans
- Generation of a synthetic CT based on multiple pre-define MR acquisitions

The Indications for Use has minor changes as clarification of wording.

VI. Comparison of Technological Characteristics with the Predicate Device

As with the predicate device syngo.via RT Image Suite SOMARIS/8 VB40, the subject device supports 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.

At a high-level a tabular summary of the subject and predicate device's technological differences is provided as Table 4 below for the software version SOMARIS/8 VB50:

Feature	Description and Comparison of the Subject Device to the Predicate Device
Routine Contouring	Routine Contouring tools (e. g. freehand drawing tools, creation of margins etc.) **Modification**:improvements in the contour interpolation tool and a tool to merge multiple structures.
Advanced Contouring	Advanced Contouring tools (automatic contouring of different structures, nudge 3D tool,contour interpolation.). Automatic contouring of pelvic and head/neck regions, support of Rapid Results Technology. **Modification:** This subject device provides the following extensions: • Automatic Contouring can be applied on further structures (thoracic and pelvic regions) • Automatic Contouring in the head/neck region, which was previously atlas-based, is now done with deep learning. The atlas method is entirely removed from this version. • Streamlined workflow to automatically adapt contours from a prior to a current planning CT

Structure Set Management	• Loading and storing of DICOM RT structure sets, creating, editing and deletion of structures and POIs. • Creating, editing and deletion of structure templates. • Customize predefined structure database with mapping to international nomenclature schemes. Modification: • multiselection of structures and POIs to apply basic operations such as copy or delete, • auto-completion for structure names, • manual and automatic save function for structure sets, • and modifications in the user interface of structure database and template creation.
Deformable Alignment	Deformable registration of images of the same patient acquired with the same or different modalities within different imaging sessions. The transformation allows for local deformation to adapt to changing anatomy (many degrees of freedom). Modification: The deformation visualization tool was simplified and now utilizes color-coded vectors to display the deformation vector field and its magnitude at the same time. The visualization is restricted to the patient outline for CT images.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

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. 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. Testing for verification and validation support the claim of substantial equivalence.

Non-Clinical Testing
This submission contains performance tests 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. 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.

Summary of the Performance Evaluation of the Algorithm
The performance of the automated organ segmentation algorithm in the subject device syngo.via RT Image Suite (software version SOMARIS/8 VB50) was evaluated and compared to the predicate device syngo.via RT Image Suite (software version SOMARIS/8 VB40).

The organ segmentation consists of a region of interest detection based on anatomical landmarks, followed by a Deep Image-to-Image Network performing the actual segmentation step. This technology was introduced in the predicate device. In the subject device, the same technology is extended to additional organs. The fundamental algorithm did not change. As described, we're using the same technology (or in other words the same algorithm) but the organ portfolio has been extended. The AI or deep learning-based algorithm has been initially cleared with the predicate device RT Image Suite SOMARIS/8 VB40 (K192065).

The segmentation algorithm of the subject device was evaluated on a test set of 112 subjects. The detection rates for the subject device were similar to those for the predicate device. Newly added organs in the subject device were detected at a rate of 100%. The segmentation quality was assessed by comparing a manually annotated ground truth with the algorithm result using the overlap measure DICE coefficient. The quantitative evaluation demonstrates non-inferior or superior performance for all organ segmentations in the subject device compared to the predicate device. The evaluation thus supports the claim of substantial equivalence.

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.

Siemens hereby certifies that syngo.via RT Image Suite will meet the following voluntary standards covering electrical and mechanical safety listed below, prior to introduction into interstate commerce:

Recognition Number	Product Area	Title of Standard	Date of Recognition	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)	01/14/2019	AAMI, ANSI, IEC
5-40	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01	06/27/2016	ISO
5-114	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015	12/23/2016	IEC

VIII. Conclusion

syngo.via RT Image Suite (software version SOMARIS/8 VB50) has the same intended use and same indication for use as the predicate device, syngo.via RT Image Suite (software version SOMARIS/8 VB40). The fundamental technological characteristics are the same as the predicate device. The result of all testing conducted was found acceptable to support the claim of substantial equivalence. 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.via RT Image Suite (software version SOMARIS/8 VB50), Siemens used the same testing with the same workflows as used to clear the predicate device. Siemens considers syngo.via RT Image Suite to be as safe, as effective and with performance substantially equivalent to the commercially available predicate device.