Siemens Medical Solutions USA, Inc.
% Ms. Kimberly Mangum
Regulatory Affairs Specialist
40 Liberty Blvd.
MALVERN PA 19355

January 12, 2018

Re: K173635
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: November 17, 2017
Received: November 24, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

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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)*

K173635

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. It also provides functionalities to create and modify simple treatment plans. Contours, images and treatment plans 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
- Management of simple 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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510(K) SUMMARY
FOR
SYNGO.VIA RT IMAGE SUITE

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: November 17, 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
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Malvern, PA 19355

Establishment Registration Number
2240869

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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:	K162370
Clearance Date:	10/25/2016
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Subsequent CFR Section:	21 CFR §892.2050

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Device Class:	Class II
Product Code:	MUJ
Subsequent Product Code:	LLZ
Recall Information:	There have been no recalls for this device

Secondary Predicate Device:

Trade Name:	syngo VSim
510(k) Number:	K151887
Clearance Date:	09/16/2015
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.5050
Device Class:	Class II
Product Code:	MUJ
Recall Information:	There have been no recalls for this device

Secondary Predicate Device:

Trade Name:	Biograph mMR with syngo MR E11P system software
510(k) Number:	K163234
Clearance Date:	02/28/2017
Classification Name:	Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1200
Device Class:	Class II
Product Code:	OUO
Subsequent Product Code:	KPS, LNH, LNI
Recall Information:	There have been no recalls for this device

Reference Device:

Trade Name:	syngo.CT Single Source Dual Energy (twin beam)
510(k) Number:	K163289
Clearance Date:	02/09/2017
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

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. The subject device syngo.via RT Image Suite with software version SOMARIS/8 VB30 is a further extension of the previously cleared primary predicate device syngo.via RT Image Suite with software version SOMARIS/8 VB20 and supports the following modifications:

1) Modified Indications for Use Statement
2) Support of software version SOMARIS/8 VB30 which supports the following functionality:
    a. Support of Beam Placement
    b. Support of Synthetic CT
    c. Support of modified contouring tools
        i. Routine Contouring
        ii. Advanced Contouring
        iii. Rapid Results Technology
    d. Support of modified structure management

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.

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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.

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. It also provides functionalities to create and modify simple treatment plans. Contours, images and treatment plans 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
- Management of simple treatment plans
- Generation of a synthetic CT based on multiple pre-define MR acquisitions

VI. Comparison of Technological Characteristics with the Predicate Device

As with the primary predicate device, 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. Software version SOMARIS/8 VB30 supports additional beam placement, synthetic CT, and modified contouring tools and structure management tools.

At a high level, the subject and predicate devices are based on the following same technological characteristics:

- Software operating platform SOMARIS/8
- Multi-modality Image Manipulation
- Multi-modality 3D and 4D visualization of images
- 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 following technological differences exist between the subject device and the primary predicate device:

- Software version SOMARIS/8 VB30
- Support of synthetic CT feature
- Support of beam placement
- Support of modified contouring tools
- Support of additional structure management tools
- Rapid Results Technology

A tabular summary of the subject and predicate device technological differences is provided as **Table 4** below:

Table 1 *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 VSim	***Secondary Predicate Device*** *Biograph mMR with syngo MR E11P system software*	**Comparison Results**
Software	SOMARIS/8 VB30	SOMARIS/8 VB20	syngo VSim VA10A	N/A	Modified from the primary predicate device to support additional functionality
Beam Placement	Creation of new geometric treatment plans for photon radiotherapy	N/A	Creation of new geometric treatment plans for photon and electron radiotherapy	N/A	Modified from the secondary predicate device to be more user intuitive
Synthetic CT	Generation of CT-density image series out of multiple MR-image series	N/A	N/A	Generation of MR-density image series out of multiple MR-image series	Modified form the secondary predicate device to support generation of CT density images
Contouring	Routine Contouring, Advanced Contouring, Contouring on 4D Image Data, Routine Structure Operations, Duplication of Structures and POIs. Rapid Results Technology	Routine Contouring, Advanced Contouring, Contouring on 4D Image Data, Routine Structure Operations, Duplication of Structures and POIs	Routine Contouring, Advanced Contouring, Routine Structure Operations, Duplication of Structures and POIs	N/A	Modified from the primary predicate device to support modified routine and advanced contouring tools
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.	Loading and storing of DICOM RT structure sets, creating, editing and deletion of structures and POIs. Creating, editing and deletion of structure templates.	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.	N/A	Modified from the predicate devices to support additional tools for contouring and structure management
Reference Point Management	Reference point creation and management	Reference point creation and management	Reference point creation and management	N/A	Same as the predicate devices
Basic Features	Routine Reading Functionality, Parallel Image Display, Routine Annotation Functionality	Routine Reading Functionality, Parallel Image Display, Routine Annotation Functionality	Routine Reading Functionality	N/A	Same as the primary predicate device
Patient Marking	Sending of reference points with offset details to a laser system	Sending of reference points with offset details to a laser system	Sending of reference points with offset details to a laser system	N/A	Same as the primary predicate device
Alignment Tools	Rigid Alignment, Deformable Alignment	Rigid Alignment, Deformable Alignment	Rigid Alignment	N/A	Same as the primary predicate device

Feature	***Subject Device*** syngo.via RT Image Suite	***Primary Predicate Device*** syngo.via RT Image Suite	***Secondary Predicate Device*** syngo VSim	***Secondary Predicate Device*** *Biograph mMR with syngo MR E11P system software*	**Comparison Results**
Dose Evaluation	Loading of any existing dose files; addition or subtraction of two dose; shows Dose Volume Histograms	Loading of any existing dose files; addition or subtraction of two dose; shows Dose Volume Histograms	N/A	N/A	Same as the primary predicate device

VII. Performance Data

Non-Clinical Testing Summary

Non-clinical tests (integration and functional) were conducted for syngo.via RT Image Suite during product development. Performance tests were conducted to test the functionality of the syngo.via RT Image Suite. The modifications described in this Premarket Notification were supported with verification/validation testing. 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. Supportive articles were provided to support specific device functionality and claims, including the Synthetic CT feature. The supportive articles provided for the synthetic CT feature demonstrates the classification of tissues for brain acquisitions method used for the synthetic CT feature included in this submission.

Siemens claims conformance to the following performance standards:

Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 – 3.20	06/27/2016	NEMA
Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	08/20/2012	IEC
General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	06/27/2016	ISO
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
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

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. Testing for verification and validation support the claim 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.

Summary

This subject device provides tool designed help the medical professional in contouring and evaluating volumes of interest, for example gross target volumes, or organs-at-risk. The fundamental software technology which is provided within the scope of the subject device is already cleared and remains unchanged in comparison to the predicate devices. The Indications for Use for the subject device has been adapted to provide a more specific description of the subject device syngo.via RT Image Suite functionality, but does not represent a new intended use. The modifications described in this Premarket Notification were supported with verification and validation testing. The Risk analysis was completed and risk control implemented to mitigate identified hazards.

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. syngo.via RT Image Suite is designed to fulfill the requirements of the applicable safety and performance standards as listed above.

VIII. Conclusions

The predicate devices were cleared based on non-clinical testing including verification and validation, phantom tests, and supportive literature. The results of these tests demonstrate that the predicate devices are adequate for the intended use. The subject device is also tested using the same methods as used for the predicate devices. The comparison of technological characteristics, non-clinical performance data, and software validation included in this submission demonstrates that the subject device is as safe and effective when compared to the predicate devices that are currently marketed for the same intended use. 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.