Siemens Medical Solutions USA Inc.
% Clayton Ginn
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K220783
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: August 8, 2022
Received: August 8, 2022

Dear Clayton Ginn:

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

Julie Sullivan
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220783

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 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 multiparametric 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.

K220783

510(K) SUMMARY
FOR
SYNGO.VIA RT IMAGE SUITE

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
Siemensstr 1
D-91301 Forchheim, Germany

Establishment Registration Number
3004977335

Submitter Contact Person:
Clayton Ginn
Regulatory Affairs Specialist
2501 North Barrington Road
Hoffman Estates, IL 60192-2061
Phone: (865) 898-2692
Email: clayton.ginn@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:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	MUJ

III. Predicate Device

Predicate Device:

Trade Name:	syngo.via RT Image Suite
510(k) Number:	K211379
Clearance Date:	07/30/2021
Classification Name:	Medical charged-particle radiation therapy system
Classification Panel:	Radiology

CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	MUJ

Reference Device:

Trade Name:	syngo.CT Bone Reading
510(k) Number:	K123584
Clearance Date:	03/12/2013
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 subject device with the current software version SOMARIS/8 VB70 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.

For the current software version SOMARIS/8 VB70 the following already cleared features have been modified:

- Patient Marking
- Contouring
- 4D Features
- Basic Features of the subject device

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 CBCT images
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- Creation of contours on images supported by the application without prior assignment of a planning CT
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- 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
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- Management of points of interest including but not limited to the isocenter
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The Indications for Use is unchanged from that of the predicate device.

VI. Comparison of Technological Characteristics with the Predicate Device

As with the predicate device syngo.via RT Image Suite SOMARIS/8 VB70, 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 VB70:

Feature	Description and Comparison of the Subject Device to the Predicate Device
Patient Marking	**General Description:** Transmission of reference points with the offset details to a movable laser system for patient marking. **Modification**: • Simplified workflow to place isocenters in the spine • Consistent user-configured default names for POIs throughout the application
Contouring	**General Description** With Contouring, the user can create, delete, and edit Volumes of Interest (VOIs). **Modification:** • Tool to convert isodose lines from a DICOM RT dose file to contours • Minor usability improvement in the structure display in the image segment
4D Features	**General Description:** The subject device provides features to handle 4D image data, such as the display of a cine loop of images acquired through gated CT. **Modification:** • Contouring on 4D Image Data improved • Lobe-based Lung Ventilation implemented
Basic Feature of syngo.via RT Image Suite	**General Description:** The set provides basic feature of the subject device. **Modification:** A software interface was added to provide additional advanced visualization and measurement tools to extend the subject device

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.

Summary of the Clinical Validation

The subject device employs an algorithm to calculate lobe-based lung ventilation based on two input CT images representing an inspiration and expiration breathing state of the patient. The algorithm contains an AI-based component, namely deep-learning based autosegmentation of lung lobes. The AI-based component is combined with the analytic calculation of a ventilation metric that is well established in scientific literature. The output is segmented lung lobes with an associated ventilation value.

The AI-based component of the algorithm is reused in unmodified form the previously cleared software version VB40A. The segmentation model was trained and validated on annotated thoracic CT scans from 8721 and 969 patients, respectively. It was tested on an independent cohort of 18 radiotherapy patients (6 female, 12 male). Test data was acquired from external clinical collaborations with radiotherapy departments in Europe and the Americas. The clinics used standard radiotherapy equipment and protocols to acquire the CT images. The test set was not made available to the model development team, thus guaranteeing its independence from the training set. Acceptance criterion for the test was unchanged geometric overlap with the annotated ground truth as measured by DICE compared to the predicate device. The test passed the acceptance criterion for all lung lobes. A mean DICE of 0.92 was achieved for the lung lobes across the test set.

In addition to the validation of the AI-based segmentation component, a clinical validation of the entire lobe-based lung ventilation algorithm was performed on 108 CT datasets from 74 individual lung radiotherapy patients (25 female, 49 male; median age: 66 yrs, range 42-87 yrs). Two subgroups were formed based on the CT acquisition technique and respective breathing mode of the patient.

In the first subgroup (4D-CT with normal breathing), the distribution of lung ventilation as produced by the predicate device was evaluated. The five lung lobes showed a similar distribution of lung ventilation with median of about 20%. The investigation demonstrated that the median ventilation is well aligned with the ground truth obtained from literature, confirming the validity of the results returned by the evaluated lung ventilation algorithm.

In the second subgroup (breathhold CT with forced breathing), a proxy for the vital capacity was calculated from the ventilation results as returned from the subject device; and correlated with vital capacity as measured by PFT (spirometry) for the same patient within one week of the CT scan. A significant Pearson correlation of $R = 0.63$ was observed ($p < 0.001$). In conclusion, the lung ventilation algorithm, based on a CT acquisition, was successfully validated by spirometry, a widely used standard method for assessment of pulmonary function.

Limitations of the clinical evaluation

- In the first subgroup, the ground truth was taken from an expected value obtained from literature, rather than establishing ground truth from each patient undergoing standard diagnostic evaluation for ventilation.
- In the second subgroup, the two clinical exams (spirometry and CT) were taken at two different time points (within one week) and under varying conditions for the patient (upright vs. supine pose, forced maximal expiration vs. instructed controlled breath hold, breathing with nose clamped vs. breathing with nose and mouth, etc)."

Because of these limitations, which may have positive or negatives effects on the results of the clinical study, the physician should be aware of these limitations and also be aware that the calculation is based on the volume and mean HU values of the lobes in the inspiration and expiration series, rather than a measurement of the air flow through each lung using an inhaled radiopharmaceutical as normally performed in nuclear medicine procedures. Thus, the ventilation results produced by RT Image Suite should not be used as the sole diagnostic tool. Clinical diagnostic evaluation of the lung ventilation is normally performed by a ventilation perfusion nuclear medicine study.

Non-Clinical Testing

This submission contains performance tests (Non-clincal test reports) 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.

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
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2015-06 (Edition 1.1)	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 VB70) has the same intended use and same indication for use as the predicate device (software version SOMARIS/8 VB60). 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, 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 devices.