Siemens Medical Solutions USA, Inc.
% Monsuru Bello
Official Correspondent
810 Innovation Drive
KNOXVILLE, TN 37932

April 26, 2024

Re: K232799
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: March 27, 2024
Received: March 27, 2024

Dear Monsuru Bello:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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.

Submission Number *(if known)*

K232799

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K232799 - 510(k) Summary

1. Identification of the Submitter

Submitter / Primary Contact Person	Monsuru K Bello Regulatory Affairs monsuru.bello@siemens-healthineers.com +1(202) 856-6099
Secondary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Submitter Address	Siemens Medical Solutions, Inc. USA Molecular Imaging 810 Innovation Drive Knoxville, TN 37932 Establishment Registration Number: 1034973
Legal Manufacturer	Siemens Healthcare GmbH Siemensstr 1 D-91301 Forchheim, Germany Establishment Registration Number: 3004977335
Importer/Distributor	Siemens Medical Solutions USA, Inc. 40 Liberty Boulevard Malvern, PA 19355 Establishment Registration Number: 2240869

2. 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

3. Predicate Devices

Predicate Device:

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

4. Device Description

The subject device with the current software version SOMARIS/8 VB80 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 changes in the current software version SOMARIS/8 VB80 are as follows:

- Modifications in Advanced Contouring: Data for training and validation of Advanced Contouring was obtained through clinical collaborations from Asia, Australia, Europe, and America to provide variability in age, gender, geographic origin, etc. Both native and contrasted CT images are included.
- Revised User Interface

5. 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
- 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

6. Indications for Use Comparison to the Predicate Device

Subject Device syngo.via RT Image Suite *(software version: SOMARIS/8 VB80)* *(510(k) number: K232799)*	**Predicate Device** syngo.via RT Image Suite *(software version SOMARIS/8 VB70)* *(510(k) number: K220783)*
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	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

7. Comparison of Technological Characteristics with the Predicate Device

The differences between the above referenced predicate device are listed at a high-level in the following table:

Feature	Subject Device	Predicate Device
	Siemens **syngo.via RT Image Suite** *(software version SOMARIS/8 VB80)*	**Siemens** **syngo.via RT Image Suite** *(software version SOMARIS/8 VB70)* *(510(k) number: K220783)*
Advanced Contouring	Advanced Contouring tools (automatic contouring of structures, nudge 3D tool, etc.). Support of Rapid Results Technology. Streamlined workflow to adapt contours from a prior to a current planning CT ("adaptive contouring"). Modifications: • The existing, cleared Advanced Contouring feature has been extended by additional anatomical structures. There are no changes on the underlying DL-based autocontouring algorithm.	Advanced Contouring tools (automatic contouring of structures, nudge 3D tool, etc.). Support of Rapid Results Technology. Streamlined workflow to adapt contours from a prior to a current planning CT ("adaptive contouring").
User Interface	syngo.via based GUI Modifications: • Minor modifications on the UI. Restructured and revised UI elements.	syngo.via based GUI

The remaining functions in syngo.via RT Image Suite remain unchanged compared to the predicate version.

- Beam Placement
- Reference Point Management
- Patient Marking
- Routine Contouring
- Advanced Contouring
- Routine Structure Operations
- Duplication of Structures and POIs
- Structure Set Management
- Rigid Alignment
- Deformable Alignment
- Dose Evaluation
- Synthetic CT
- Contouring on 4D Image Data
- Lobe-Based Lung Ventilation
- Routine Reading Functionality

- Parallel Image Display
- Routine Annotation Functionality

8. Performance Data

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

Non-Clinical Testing - Software Verification and Validation
Software Documentation for Enhanced documentation Level per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is also included as part of this submission. 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.

Performance Evaluation of the Algorithm
The AI-based autocontouring feature of syngo.via RT Image Suite was tested on 413 subjects. The test data was generated from an independent set that was not seen by the model during training stage to cover a wide range of CT scanners and typical CT acquisition and reconstruction parameters. The general guideline was to reserve 20% of the available data for validation. The test data covers:

- Regional distribution (Europe: IT, PT, CH, UK, NL, DE; North America: US, CA; South America: BR; Australia, Asia: JP, IN)
- Demographic distribution: Male/female
- Distribution by manufacturer of the scanner: GE, Siemens, Philips
- Distribution in protocols of different slice thicknesses: between < 1 mm till > 3 mm
- Subgroup analysis regarding manufacturer, slice thickness and gender did not show any confounder.

Table 1: Distribution of validation data across subgroups

Subgroup	# Validation data sets
Data Source	Europe: 58, US: 165, Canada: 39, South America: 78, Australia: 28, Asia: 33, unknown: 12
Body Region	Head&Neck: 113, Thorax&Abdomen: 216, Pelvis: 84
Gender	Male: 188, female: 174. Unknown: 51
Age	<=30: 1, [30-50]: 6, [50;70]: 46, >70: 20, unknown: 340
Slice thickness (in mm)	<=1:19, (1,2]: 207, (2,3]: 168, >3: 19
Manufacturer	Siemens: 126, GE: 77, Philips: 140, unknown/others: 70

Manual ground-truth segmentations were annotated by an expert team based on well accepted international contouring guidelines, followed by a rigorous independent quality assessment. The testing ensures the quantitative performance of the resulting segmentations by comparing them to the manually annotated ground truth based on the commonly used overlap metric Dice coefficient . All tests passed the defined acceptance criteria on the geometric overlap with the ground truth. The evaluation results confirm the clinical safety and performance of the autocontouring feature.

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 meets the following FDA Recognized Consensus standards listed below:

Standard	Version	Content	FDA Recognition Number (if applicable)
ANSI AAMI IEC 62304	:62304:2006/A 1:2016	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	13-79
NEMA PS 3.1 - 3.20 2022d	:2022	Digital Imaging and Communications in Medicine (DICOM) Set	12-349
ISO 14971	:2019	Application of Risk Management to Medical Devices	5-125
IEC 62366-1	Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 15223-1	Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
ISO 20417	First edition 2021-04 Corrected version 2021-12	Medical devices - Information to be supplied by the manufacturer	5-135

9. Conclusion

syngo.via RT Image Suite has the same intended use and indication for use 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, clinical and 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. 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.