



September 18, 2019

Siemens Medical Solutions USA, Inc.
% Ms. Veronica Padharia
Regulatory Affairs Specialist
2501 N Barrington Road
HOFFMAN ESTATES IL 60192

Re: K192065

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: July 31, 2019
Received: August 1, 2019

Dear Ms. Padharia:

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/pmnmn.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,

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

Indications for Use

510(k) Number (if known)

K192065

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**

K192065

Submitted by:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Date Prepared: June 25, 2019

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

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Establishment Registration Number

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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
Device Class: Class II
Product Code: MUJ

III. Predicate Device

Predicate Device:

Trade Name: syngo.via RT Image Suite
510(k) Number: K173635
Clearance Date: 01/12/2018
Classification Name: System, Planning, Radiation Therapy Treatment
Classification Panel: Radiology
CFR Section: 21 CFR §892.5050

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

IV. Device Description

The subject device with the current software version SOMARIS/8 VB40 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. At a high-level, the following features have been modified:

1. Beam Placement
2. Reference Point Management
3. Patient Marking
4. Contouring
5. Structure Set Management

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 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
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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
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- 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 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.

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 VB40:

| Feature | Comparison of the Subject Device to the Predicate Device |
|----------------------------|--|
| Beam Placement | <p>Creation of new geometric treatment plans for photon radiotherapy. The syngo.via workflow supports a more user intuitive workflow (i.e. a more modern look and feel).</p> <p>Modification: Beam placement auto shape now also allows in creating rectangular block fields.</p> |
| Reference Point Management | <p>Reference Point Management allows the user to edit the position, color, and type of Points of Interest (POI).</p> <p>Modification: The workflow for reference point creation has been simplified and a streamlined workflow for breast iso-centering has been implemented.</p> |
| Patient Marking | <p>Sending of reference points with offset details to a laser system.</p> <p>Modification: Support of simplified workflow for breast iso-centering. Enabled by combining improvements in iso-centering contouring the breast. It identifies the breast boundaries and suggests a proper iso-center for breast treatment.</p> |
| Routine Contouring | <p>Routine Contouring tools (e. g. freehand drawing tools, creation of margins etc.)</p> <p>Modifications include capability of interpolating contours, 3D Pan/Scale options, and option to add rectangular and ellipse as contour shapes, improvement in nudge tool to enable auto filling of the inner part of a closed contour, and restricting the margin extension to external contour.</p> |
| Advanced Contouring | <p>Advanced Contouring tools (automatic contouring of different structures, nudge 3D tool, contour interpolation etc.). Automatic contouring of pelvic and head/neck regions, support of Rapid Results Technology.</p> <p>Modification: This subject device provides the following extensions:</p> <ul style="list-style-type: none"> • Automatic Contouring can be applied on further structures (thoracic and abdominal regions) • A new deep learning-based approach that uses an adversarial network has been implemented |
| Structure Set Management | <p>The Structure Set Management provides the following functionality:</p> <ul style="list-style-type: none"> • 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. <p>Modification includes simplifying the user interface.</p> |

Table 1 Differences in Technical Characteristics

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 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.

Clinical Testing Summary

The results of the evaluation show improved performance of the subject device syngo.via RT Image Suite (software version SOMARIS/8 VB40), compared to the predicate device syngo.via RT Image Suite (software version SOMARIS/8 VB30). The detailed report is provided in support of the device modifications.

The organ-at-risk (OAR) segmentation of the subject device consists of a region of interest detection based on anatomical landmarks, followed by a Deep Image-to-Image Network performing organ segmentation. Those both parts of the segmentation algorithm were validated separately using a testing set of 32 datasets.

The detection rate of the subject device improved for the OAR Brain, Liver, Kidney Left, and Kidney Right compared to the predicate device, achieving 100% for all evaluated organs.

The segmentation quality was assessed by comparing a manually annotated ground truth with the algorithm result using the distance measure Average Symmetric Surface Distance (ASSD) and the overlap measure DICE coefficient. The mean ASSD computed for the subject device ranged between 0.64 mm (for Femur Head Right) and 3.04 mm (for Heart) and improved for all evaluated OAR. The mean DICE coefficient ranged between 0.85 (for Prostate and Rectum) and 0.97 (for Heart). The results for mean ASSD and mean DICE coefficient both demonstrate the improved segmentation quality provided by the subject device compared to the predicate device.

Standards

Siemens claims conformance to the following performance standards:

| Recognition Number | Product Area | Title of Standard | 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 |
| 13-32 | Software | Medical Device Software –Software Life Cycle Processes; 62304:2006 (1 st Edition) | 08/20/2012 | AAMI, ANSI, IEC |
| 5-40 | Software/ Informatics | Medical devices – Application of risk management to medical devices; 14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |
| 5-114 | General I (QS/RM) | Medical devices - Part 1: Application of usability engineering to medical devices IEC 62366-1:2015 | 06/27/2016 | IEC |

Summary

This subject device provides tools 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 device. The Indications for Use for the subject device remains unchanged. The modifications described in this Premarket Notification were supported with verification and validation testing and clinical performance evaluation. The Risk analysis was completed and risk control implemented to mitigate identified hazards.

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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 device was cleared based on non-clinical testing including verification and validation, phantom tests, and supportive literature. The results of these tests demonstrate that the predicate device is 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.