



March 18, 2026

Varian Medical Systems, Inc.
Lynn Allman
Sr. Director, Regulatory Affairs
3100 Hansen Way
Palo Alto, California 94304

Re: K252304

Trade/Device Name: syngo.via RT Image Suite VC10
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: February 17, 2026
Received: February 17, 2026

Dear Lynn Allman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

Daniel M. Krainak, Ph.D.
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

Indications for Use

510(k) Number (if known)

K252304

Device Name

syngo.via RT Image Suite VC10

Indications for Use (Describe)

syngo.via RT Image Suite VC10 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 (not all of them might be available at each customer):

- Multimodality 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 and MR images, including known (diagnosed) brain metastases
- Creation of contours on images supported by the application without prior assignment of a planning CT or planning MR
- 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 pre-defined 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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Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for *syngo.via* RT Image Suite VC10

I. Submitter and Manufacturer Information

Submitter Name and Address	Varian Medical Systems 3100 Hansen Way Palo Alto, CA 94304
Contact Name	Lynn, Allman, PhD., Senior Director Regulatory Affairs
Email and Phone	submissions.support@varian.com (650) 424-5369
Date Prepared	Feb 13 th 2026
Manufacturer Name and Address	Siemens Healthcare GmbH Henkestr. 127 91052 Erlangen Germany

II. Device Information

Proprietary Name: *syngo.via* RT Image Suite VC10
 Common/Usual Name: *syngo.via* RT Image Suite VC10
 Classification Name: System, Planning, Radiation Therapy Treatment
 Regulation: 21 CFR 892.5050
 Product Code: MUJ
 Device Class: Class II

III. Predicate Device

syngo.via RT Image Suite VB80 (K232799)

Reference Device : VBrain (K203235)

IV. Device Description

syngo.via RT Image Suite VC10 is an image analysis and radiation therapy preparation software that provides multimodality image viewing, registration, segmentation, synthetic CT generation, and patient-marking workflows. Within the Medical device *syngo.via* RT Image Suite VC10 the name 'CT Sim&Go' is used. CT Sim&GO is the name used for *syngo.via* RT Image Suite VC10 when it is deployed in the CT scanner workflow. CT Sim&GO is not a device of its own. CT Sim&GO is a subset of *syngo.via* RT Image Suite VC10 functionalities that can be accessed from the CT scanner workplace. More precisely it comprises the Patient Marking and Beam Placement modules of *syngo.via* RT Image Suite VC10. The current submission includes modifications affecting the following functionalities:

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syngo.via RT Image Suite VC10

MR Autocontouring

The AI-based MR autocontouring functionality has been introduced to include segmentation of previously diagnosed brain metastases, in addition to MR-based segmentation of brain OARs and male pelvis OARs.

The metastasis-specific model is restricted to identification of metastases already diagnosed by a clinician, and the software does not provide diagnostic capability or detect new or unknown lesions.

These contours remain fully editable by the user.

CT Autocontouring

syngo.via RT Image Suite VC10 includes 29 new organs and structures for deep-learning-based CT autocontouring.

The underlying DL architecture is unchanged; however, additional segmentation guidelines and organ-coverage expansion were incorporated.

Improvements to Isocenter Definition & Patient Marking

The patient-marking workflow includes semi-automated isocenter estimation for breast (originally cleared under K192065) and vertebral regions (originally cleared under K220783). New capability to send the coordinates from a movable laser positioning system to the syngo.via RT Image Suite VC10, enabling a workflow of setting isocenter directly on the skin and transferring it to the planning images.

Synthetic CT

The synthetic CT feature was updated to include a new 3D deep-learning-based algorithm for brain and pelvis, replacing the prior 2D model and improving HU accuracy and geometric fidelity.

V. Indications for Use

syngo.via RT Image Suite VC10 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.

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The software combines the following digital image processing and visualization tools (not all of them might be available at each customer):

- Multimodality 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 and MR images, including known (diagnosed) brain metastases
- Creation of contours on images supported by the application without prior assignment of a planning CT or planning MR
- 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 pre-defined MR acquisitions

VI. Comparison of Technological Characteristics with the Predicate Device

The modified device, referred to as the “subject device” throughout this summary, is release version VC10 of the *syngo.via* RT Image Suite with additional software changes incorporated since the release version of the predicate device, version VB80 (K232799).

The subject device (VC10) maintains the same fundamental technology and operational principles as the predicate device *syngo.via* RT Image Suite VB80 (K232799). The following updates have been added to clearly capture changes introduced in VC10 that were not cleared previously:

Metastasis Contouring

The predicate device did not include MR autocontouring

Laser-to-Software and Software-to-Laser Isocenter Transfer

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VC10 adds the ability to receive isocenter coordinates from RTP laser systems in addition to sending them extending interoperability.

Synthetic CT

VC10 replaces the prior 2D synthetic CT algorithm with an enhanced 3D Deep learning model, improving accuracy and robustness for brain and pelvis.

The different technical characteristics do not raise different questions about safety and effectiveness. These modifications raise similar questions relating to software performance, software interoperability, and usability. These considerations of safety and effectiveness were also applicable to the predicate device.

Comparison of Subject Device to Predicate Device syngo.via RT Image Suite VC10 and syngo.via RT Image Suite VB80

No.	Specification	Predicate Device (Primary)	Device Under Evaluation	Equivalency
		syngo.via RT Image Suite (VB80) 510(k) Id # K232799	Syngo.via RT Image Suite VC10	
1.0	Clinical Characteristics			
1.1	Intended Purpose	Image analysis software for evaluating image data sets and preparing them for further use in therapy.	Image analysis software for evaluating image data sets and preparing them for further use in therapy.	Equivalent
1.2	Intended Use	syngo.via RT Image Suite is intended to be used by trained medical professionals including, but not limited to, medical physicists, RT technologists, physicians, radiologists, nuclear medicine physicians, and radiation oncologists. syngo.via RT Image Suite is a medical application for viewing, manipulation, 3D and 4D visualization, and comparison of medical images from multiple imaging modalities. The application enables the registration of images and provides tools to help the user to identify volumes, regions and points of interest inside the patient anatomy. The application also enables the creation of simple geometric plans. The application may assist in the preparation of further radiation therapy treatment planning. The application supports	syngo.via RT Image Suite is intended to be used by trained medical professionals including, but not limited to, medical physicists, RT technologists, physicians, radiologists, nuclear medicine physicians, and radiation oncologists. syngo.via RT Image Suite is a medical application for viewing, manipulation, 3D and 4D visualization, and comparison of medical images from multiple imaging modalities. The application enables the registration of images and provides tools to help the user to identify volumes, regions and points of interest inside the patient anatomy. The application also enables the creation of simple geometric plans. The application may assist in the preparation of further radiation therapy treatment planning. The application supports anatomical datasets from CT, MR, CBCT, as	Equivalent

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syngo.via RT Image Suite VC10

		anatomical datasets from CT, MR, CBCT, as well as functional data, such as 4D CT, 3D/4D PET/CT, and 4D MRI.	well as functional data, such as 4D CT, 3D/4D PET/CT, and 4D MRI.	
1.3	Indications for Use	<i>syngo.via</i> 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.	<i>syngo.via</i> 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	Substantially Equivalent Updated with the inclusion of MR Images

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		The software combines the following digital image processing and visualization tools: • Multimodality 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 multimodality image fusion	image processing and visualization tools (not all of them might be available at each customer): • Multimodality 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 and MR images, including known (diagnosed) brain metastases • Creation of contours on images supported by the application without prior assignment of a planning CT or planning MR • 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 multimodality image fusion	
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		• 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	• 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 pre-define MR acquisitions	
1.4	Clinical condition intended to diagnose, treat or manage	Not restricted	Not restricted	Equivalent
1.5	Intended patient population	The intended patient population is not subject to any restrictions. However, automation support provided works best with adult patients.	The intended patient population is not subject to any restrictions. However, functionality like Auto-Contouring and Lung Ventilation work best with adult patients.	Substantially Equivalent minor deviation in wording
1.6	Contraindications	There are no known specific situations that contraindicate the use of this device.	There are no known specific situations that contraindicate the use of this device.	Equivalent
1.7	Operating Environment	The task is designed to be used embedded in the scanner console or in a workstation next to it to perform patient virtual simulation in the radiation therapy context. It can also be used in the contouring room or in the physicians' office to perform treatment preparation (registration, contouring,	The task is designed to be used embedded in the Reading/Control Room on a scanner console or in a workstation next to it to perform patient virtual simulation in the radiation therapy context. It can also be used in the Reading Room (contouring room or in the physicians' office) to perform treatment preparation (registration, contouring,	Substantially Equivalent minor deviation in wording

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		adaption) or treatment assessment (decision on treatment strategy).	adaption) or treatment assessment (decision on treatment strategy).	
1.	Intended Users	Trained medical professionals including, but not limited to, medical physicists, RT technologists, physicians, radiologists, nuclear medicine physicians, and radiation oncologists.	Qualified persons with the necessary knowledge in accordance with country-specific regulations , for example, radiotherapy technologists, medical physicists, clinical administrators, or radiation oncologists	Substantially Equivalent minor deviation in wording
2.0	Technical Characteristics			
2.1	Basic Features of the Subject Device			
	Routine Reading Functionality	VRT, MPR, MIP, thin VRT, thick MPR, Interaction: zoom, pan, rotate	VRT, MPR, MIP, thin VRT, thick MPR, Interaction: zoom, pan, rotate	Equivalent
	Parallel Display	Parallel Image Display, Image Visualization, Image Fusion, Correlated Cursors	Parallel Image Display, Image Visualization, Image Fusion, Correlated Cursors	Equivalent
	Routine Annotation Functionality	Distance line, ROI, VOI, pixel lens, angle; findings	Distance line, ROI, VOI, pixel lens, angle; findings	Equivalent
2.2	Image Registration			
	Rigid Alignment	Rigid registration of images of the same patient acquired with the same or different modalities within the same or different imaging sessions. The transformation includes only translation and rotation (6 degrees of freedom).	Rigid registration of images of the same patient acquired with the same or different modalities within the same or different imaging sessions. The transformation includes only translation and rotation (6 degrees of freedom).	Equivalent
	Deformable Alignment	Deformable registration of images of the same patient acquired with the same or different modalities within different imaging	Deformable registration of images of the same patient acquired with the same or different modalities within different imaging sessions.	Equivalent

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		sessions. The transformation allows for local deformation to adapt to changing anatomy (many degrees of freedom). The feature includes a tool for visual quality assurance.	The transformation allows for local deformation to adapt to changing anatomy (many degrees of freedom). The feature includes a tool for visual quality assurance.	
2.3	Contouring			
	Routine Contouring	Routine Contouring tools (e. g. freehand drawing tools, creation of margins, tool to convert isodose lines from a DICOM RT dose file to contours etc.)	Routine Contouring tools (e. g. freehand drawing tools, creation of margins etc.) A tool was added to convert isodose lines from a DICOM RT dose file to contours.	Equivalent
	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").	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"). Additional structures and organs were added for Auto Contouring to extend the organ coverage and included additional segmentation guidelines for CT images and Inclusion of MR Images (MR autocontouring including brain metastasis) (The underlying deep learning technology for this extension is unchanged. It reuses the same technology which was available in prior versions of the auto segmentation feature).	Existing feature enhanced

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			Brain metastasis specific contouring model is limited to previously diagnosed metastases, using deep learning segmentation. Note: Brain metastases – only on MR Images)	
	Contouring on 4D Image Data	Contouring tools on 4D image data (e. g. display of a cine loop of images acquired through gated CT etc.)	Contouring tools on 4D image data (e. g. display of a cine loop of images acquired through gated CT etc.)	Equivalent
	Routine Structure Operations	Structure editing tools (e. g. expansion or shrinking of a structure).	Structure editing tools (e. g. expansion or shrinking of a structure).	Equivalent
	Duplication of Structures and POIs	Duplication of structures and POIs inside the same structure set.	Duplication of structures and POIs inside the same structure set.	Equivalent
2.4	Structure Set Management			
	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. • Customize predefined structure database with mapping to international nomenclature schemes.	Equivalent
2.5	Reference Point Management			
	Reference Point Management	Reference point creation and management	Reference point creation and management	Equivalent
2.6	Patient Marking			
	Patient Marking	Sending of reference points with offset details to a laser system.	Sending and receiving of reference points with offset details and coordinates to and	Minor difference -

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		• Inclusion of a simplified workflow to place isocenters in the spine • Consistent use of user-configured default names throughout the application	from a movable laser system. • Inclusion of a simplified workflow to place isocenters in the spine • Consistent use of user-configured default names throughout the application	Existing feature enhanced
2.7	Dose Evaluation			
	Dose Evaluation	Loading of any existing dose files; addition or subtraction of two dose; show Dose Volume Histograms	Loading of any existing dose files; addition or subtraction of two dose; show Dose Volume Histograms	Equivalent
2.8	Beam Placement			
	Beam Placement	Creation of new geometric treatment plans for photon radiotherapy	Creation of new geometric treatment plans for photon radiotherapy	Equivalent
2.9	Synthetic CT			
	Synthetic CT	Generation of CT-density image series (2D model) out of multiple MR-image series for Pelvis and Brain.	New Synthetic CT algorithm (3D model) for Pelvis and Brain was provided	Existing feature enhanced
2.10	Lung Ventilation			
	Lung Ventilation	Calculation of lobe-based lung ventilation from an inspiration and expiration CT scan	Calculation of lobe-based lung ventilation from an inspiration and expiration CT scan	Equivalent
2.11	Software			
	User Interface	<i>syngo.via</i> based GUI	<i>syngo.via</i> based GUI	Equivalent
	Archiving / Storing	MOD, CD-R, film; DVD	MOD, CD-R, film; DVD	Equivalent
	Communication	DICOM Compatible	DICOM Compatible	Equivalent
2.12	Model support			
	Model support	CT Scanners, <i>syngo.via</i> platform	CT Scanners, <i>syngo.via</i> platform	Equivalent

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Comparison of Contour Metastases for VBrain and syngo.via RT Image Suite VC10

Specification	Reference Device VBrain (K203235)	Device Under Evaluation syngo.via RT Image Suite VC10	Equivalency
Intended Use	Assists trained medical professionals in RT planning by providing initial contours for known brain tumors.	Software for multimodality viewing, registration, and autocontouring including brain metastases.	Similar
Clinical Workflow Role	Provides initial GTV contours requiring clinician review.	Provides editable automated contours; clinician review required.	Similar

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syngo.via RT Image Suite VC10

Specification	Reference Device VBrain (K203235)	Device Under Evaluation syngo.via RT Image Suite VC10	Equivalency
Tumor Types Supported	Brain metastases, meningiomas, acoustic neuromas.	Brain metastases and brain OARs.	Similar
Imaging Modalities	T1 CE MRI	CT, MRI, CBCT, PET/CT, etc.	Similar
AI/ML Technology	Deep learning neural networks.	3D UNet/DI2IN-based DL models.	Similar
User Control	Fully editable	Fully editable	Similar
Performance Sensitivity	90.3%	92.5%	Similar
False Positive Rate	0.681 tumors/case	1.30	Similar
Dice Coefficient	0.793	0.74	Similar
Hausdorff Distance	5.0% in terms of lesion size	1.41 mm (HD95)	Similar

VII. Summary of Performance Testing (Non-Clinical Testing)

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

Software Verification and Validation Testing:

Software verification and validation was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."* The software for this device was considered as a "major" level of concern. The software development and validation were performed in accordance with recognized standards including IEC 62304, ISO 14971, and applicable FDA-recognized consensus standards.

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Cybersecurity and Interoperability requirements were assessed per FDA guidance's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", "Postmarket Management of Cybersecurity in Medical Devices", "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices".

Verification and validation testing demonstrated that the software met all specified requirements. All test cases passed predefined acceptance criteria. The testing supports the safety, effectiveness, and substantial equivalence of the device.

Test results demonstrate conformance to applicable requirements and specifications.

No animal studies or clinical tests have been included in this pre-market submission. However, usability validation was successfully performed and demonstrated that intended users can safely and effectively operate the modified features without patterns of use error. This is consistent with the nonclinical validation showing equivalent or improved performance relative to the predicate.

Scope and Goals of Testing and Criteria

Each algorithm was evaluated using quantitative metrics appropriate for its output:

- CT auto-contouring: DICE coefficient and ASSD vs. expert ground truth.
- MR Brain Metastasis: DICE, Hausdorff Distance, false-positive rate per case, sensitivity.
- MR OAR Models (Brain, Pelvis): DICE and ASSD.
- Synthetic CT: HU accuracy and geometric fidelity.
- Semi-automated isocenter estimates or defining isocenters via RTP lasers: Isocenter placed within defined anatomical structure (breast, vertebrae)

All models met predefined acceptance criteria based on historical SYNGO.VIA RT IMAGE SUITE VC10 validation thresholds and clinical guideline requirements.

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Clinical Data Summary

Algorithm performance was evaluated using independent test datasets comprising a total of 760 patients subjects, distributed across the following models and features:

Model / Feature	Number of Subjects
CT auto-contouring	469
MR brain metastasis model	30
MR brain organs-at-risk (OAR) model	46
MR pelvis OAR model	154
Synthetic CT model	51
Semi-automated isocenter estimation / laser-based isocenter definition (breast)	10
Semi-automated isocenter estimation / laser-based isocenter definition (vertebra)	10

All test datasets were independent of training datasets.

Demographics and Subgroup Representation

Each dataset included adult patients with distributions across gender and age ranges relevant to the intended use. Subgroup analyses were performed to assess potential confounding factors. For CT auto-contouring, subgroups included scanner manufacturer, slice thickness, and gender. For MR-based models, subgroups included scanner manufacturer, magnetic field strength (1.5T and 3T), and gender. No clinically relevant confounders were identified.

Imaging Equipment and Protocols

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Image data were collected across multiple scanner vendors (Siemens, GE, and Philips) and included variation in relevant acquisition parameters such as slice thickness, magnetic field strength, and MR sequence type, as applicable to each model.

Reference Standard and Data Independence

Ground truth contours were generated by expert clinicians using well-established international contouring guidelines and underwent independent quality assurance reviews. All algorithms were evaluated using test datasets that were not used during model training, with test data drawn from separate patient cohorts, clinical sites, or imaging systems where applicable.

Training Data Overview

Training datasets consisted of curated, multicenter CT and MR image collections with expert-annotated reference standards and standardized preprocessing. The training data included a range of manufacturers, acquisition settings, and clinical conditions relevant to the intended use.

Performance Evaluation of the Algorithm:

CT auto-contouring

The AI-based auto-contouring feature of *syngo.via* RT Image Suite VC10 was tested on 469 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 5 mm

Subgroup analysis regarding manufacturer, slice thickness and gender did not show any confounder.

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Distribution of test data across subgroups for CT auto-contouring

Subgroup	# Test data sets
Data Source	Europe: 110, US: 149, Canada: 56, South America: 83, Australia: 29, Asia: 33, unknown: 13
Body Region	Head&Neck: 114, Thorax&Abdomen: 266, Pelvis: 93
Gender	Male: 199, female: 216, Unknown: 58
Age	<=30: 1, [30-50]: 6, [50;70]: 46, >70: 22, unknown: 398
Slice thickness (in mm)	<=1:20, (1,2]: 220, (2,3]: 213, >3: 20
Manufacturer	Siemens: 148, GE: 100, Philips: 149, unknown/others: 76

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.

Analysis was performed on DICE (Dice Similarity Coefficient) and ASSD (Average symmetric surface distance)

DICE: measures the volumetric overlap between algorithm result and manual ground truth annotation; value range between 0 (no overlap) and 1 (full overlap).

ASSD: measures the average surface-to-surface distance in mm between algorithm result and manual ground truth annotation.

While the DICE coefficient is very commonly used for the purpose of comparing segmentations, its meaningfulness is limited for small structures. For small organs, the ASSD is the more suitable metric.

The performances from predicate device (for organs available in predicate and subject device) and FDA cleared /scientific literature (for new organs) were used as reference standards.

Quantitative evaluation of organs available in predicate and subject device

The **acceptance criterion** was defined in the following way:

- Statistical non-inferiority of the Dice score compared with the reference predicate.

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Non-inferiority is defined such that the lower 95th percentile confidence bound of the subject device is greater than the mean reference performance subtracted by a 10% margin.

Test results: passed for all organs. Table below shows the performance results.

Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
Body	46	0.99	0.003	0.99
Spinal Canal	27	0.85	0.073	0.82
Spinal Cord	39	0.67	0.102	0.64
Brain	20	0.98	0.005	0.98
Brainstem Brouwer et al.	20	0.89	0.024	0.88
Brainstem DAHANCA ¹	30	0.88	0.025	0.88
Cochlea Left	25	0.75	0.164	0.68
Cochlea Right	25	0.8	0.049	0.78
Eye Globe Left	20	0.89	0.038	0.88
Eye Globe Right	20	0.89	0.027	0.88
Glottis Brouwer et al.	20	0.7	0.103	0.65
Glottis DAHANCA ¹	30	0.68	0.087	0.65
Lens Left	20	0.68	0.192	0.59
Lens Right	20	0.67	0.121	0.61
Lips	20	0.79	0.072	0.76
LN Level Ia Submental Triangle	59	0.64	0.157	0.6
LN Level Ib Submandibular Triangle Left	59	0.8	0.063	0.79

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
LN Level Ib Submandibular Triangle Right	58	0.77	0.086	0.75
LN Level II Upper Jugular Nodes Left	59	0.82	0.051	0.81
LN Level II Upper Jugular Nodes Right	59	0.8	0.063	0.78
LN Level III Middle Jugular Nodes Left	59	0.79	0.067	0.77
LN Level III Middle Jugular Nodes Right	59	0.77	0.085	0.75
LN Level IVa Lower Jugular Group Left	59	0.71	0.109	0.68
LN Level IVa Lower Jugular Group Right	59	0.73	0.084	0.71
LN Level IVb Medial Supraclavicular Group Left	59	0.66	0.159	0.62
LN Level IVb Medial Supraclavicular Group Right	59	0.7	0.11	0.67
LN Level IX Bucco-facial Group Left	59	0.64	0.08	0.62
LN Level IX Bucco-facial Group Right	59	0.62	0.096	0.59
LN Level V Posterior Triangle Group Left	59	0.71	0.117	0.68
LN Level V Posterior Triangle Group Right	59	0.69	0.122	0.66
LN Level Vc Lateral Supraclavicular Group Left	59	0.56	0.156	0.52
LN Level Vc Lateral Supraclavicular Group Right	59	0.61	0.123	0.57
LN Level VIa Anterior Jugular Nodes	59	0.7	0.066	0.69
LN Level VIb Prelaryngeal, Pretracheal, & Paratracheal Nodes	59	0.66	0.109	0.64
LN Level VIIa Retropharyngeal Nodes Left	59	0.53	0.1	0.5
LN Level VIIa Retropharyngeal Nodes Right	59	0.49	0.149	0.45

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
LN Level VIIb Retro-styloid Nodes Left	59	0.73	0.079	0.71
LN Level VIIb Retro-styloid Nodes Right	59	0.74	0.095	0.71
LN Level VIII Parotid Group Left	59	0.85	0.037	0.84
LN Level VIII Parotid Group Right	59	0.84	0.042	0.83
LN Level Xa Retroauricular & Subauricular Nodes Left	59	0.69	0.099	0.66
LN Level Xa Retroauricular & Subauricular Nodes Right	59	0.73	0.075	0.71
LN Level Xb Occipital Nodes Left	59	0.57	0.111	0.54
LN Level Xb Occipital Nodes Right	59	0.56	0.136	0.52
Mandible	20	0.88	0.028	0.87
Optic Chiasm	20	0.37	0.183	0.29
Optic Nerve Left	20	0.63	0.121	0.57
Optic Nerve Right	20	0.63	0.103	0.58
Oral Cavity	20	0.89	0.049	0.87
Parotid Gland Left	20	0.85	0.081	0.82
Parotid Gland Right	20	0.85	0.072	0.81
Pharyngeal Constrictor Muscle Inferior	30	0.78	0.049	0.76
Pharyngeal Constrictor Muscle Middle	30	0.67	0.076	0.64
Pharyngeal Constrictor Muscle Superior	30	0.66	0.056	0.64
Submandibular Gland Left	19	0.87	0.045	0.84
Submandibular Gland Right	15	0.85	0.066	0.82
Supraglottic Larynx Brouwer et al.	20	0.77	0.091	0.73
Supraglottic Larynx DAHANCA ¹	30	0.8	0.059	0.78

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
Thyroid	30	0.84	0.034	0.83
Aorta	35	0.87	0.032	0.86
Brachial Plexus Right	20	0.66	0.051	0.63
Brachial Plexus Left	20	0.63	0.089	0.59
Chest Wall Left	28	0.92	0.016	0.92
Chest Wall Right	28	0.93	0.013	0.92
Esophagus RTOG	34	0.81	0.059	0.79
Esophagus DAHANCA ¹	30	0.86	0.042	0.84
Female Breast Left RTOG	8	0.89	0.049	0.85
Female Breast Left ESTRO ¹	28	0.91	0.034	0.89
Female Breast Right RTOG	7	0.85	0.066	0.79
Female Breast Right ESTRO ¹	28	0.91	0.035	0.89
LN Axilla Level I Left	24	0.81	0.055	0.79
LN Axilla Level I Right	24	0.8	0.072	0.77
LN Axilla Level II Left	24	0.79	0.068	0.76
LN Axilla Level II Right	24	0.78	0.07	0.75
LN Axilla Level III Left	24	0.75	0.042	0.74
LN Axilla Level III Right	24	0.76	0.078	0.73
LN Internal Mammary Left	24	0.59	0.081	0.55
LN Internal Mammary Right	24	0.63	0.096	0.59
LN Supraclavicular Left	24	0.79	0.085	0.76
LN Supraclavicular Right	24	0.8	0.068	0.77
Lung Lobe Left Lower	18	0.9	0.125	0.84
Lung Lobe Left Upper	18	0.94	0.073	0.91

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
Lung Lobe Right Lower	17	0.93	0.045	0.9
Lung Lobe Right Middle	18	0.89	0.079	0.85
Lung Lobe Right Upper	18	0.93	0.053	0.91
Proximal Bronchial Tree	27	0.84	0.051	0.82
Pulmonary Artery	27	0.8	0.058	0.78
Rib Left 1	19	0.84	0.043	0.82
Rib Left 10	19	0.77	0.189	0.68
Rib Left 11	19	0.77	0.191	0.68
Rib Left 12	18	0.8	0.073	0.76
Rib Left 2	19	0.83	0.075	0.8
Rib Left 3	19	0.82	0.038	0.8
Rib Left 4	19	0.83	0.033	0.81
Rib Left 5	19	0.83	0.032	0.82
Rib Left 6	19	0.84	0.024	0.83
Rib Left 7	19	0.83	0.031	0.82
Rib Left 8	19	0.82	0.036	0.8
Rib Left 9	19	0.82	0.023	0.81
Rib Right 1	19	0.84	0.051	0.81
Rib Right 10	19	0.79	0.194	0.69
Rib Right 11	19	0.78	0.193	0.68
Rib Right 12	18	0.82	0.044	0.8
Rib Right 2	19	0.87	0.027	0.85
Rib Right 3	19	0.85	0.039	0.83
Rib Right 4	19	0.86	0.027	0.85

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
Rib Right 5	19	0.86	0.026	0.85
Rib Right 6	19	0.86	0.026	0.85
Rib Right 7	19	0.85	0.031	0.84
Rib Right 8	19	0.81	0.109	0.76
Rib Right 9	19	0.79	0.2	0.69
Ribs	19	0.88	0.025	0.87
Sternum	34	0.88	0.032	0.87
Trachea	27	0.89	0.046	0.87
Vena Cava Inferior	27	0.76	0.128	0.71
Vena Cava Superior	27	0.79	0.069	0.76
Atrium Left	57	0.86	0.048	0.85
Atrium Right	57	0.79	0.089	0.77
Heart	57	0.93	0.02	0.93
CA Left Anterior Descending Artery (LAD)	55	0.42	0.097	0.39
Ventricle Left Endocardium	57	0.84	0.054	0.82
Ventricle Left	57	0.86	0.041	0.85
Ventricle Right	57	0.83	0.034	0.83
Abdominopelvic Cavity	21	0.96	0.032	0.94
Bowel Large	102	0.9	0.045	0.89
Bowel Small	76	0.89	0.042	0.88
Duodenum	76	0.77	0.104	0.75
Kidney Left	16	0.93	0.019	0.92
Kidney Right	16	0.91	0.07	0.87
Liver	23	0.96	0.013	0.95

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Structure	# Test Cases	DICE		
		Mean	Std.Dev	Lower 95th % Confidence Interval
Pancreas	31	0.68	0.138	0.63
Stomach	31	0.91	0.043	0.89
Spleen	21	0.93	0.022	0.92
Bladder	20	0.95	0.052	0.93
LN Common Iliac Left	19	0.85	0.053	0.82
LN Common Iliac Right	19	0.82	0.048	0.8
LN External Iliac Left	19	0.89	0.036	0.87
LN External Iliac Right	19	0.88	0.031	0.87
LN Internal Iliac Left	19	0.83	0.072	0.79
LN Internal Iliac Right	19	0.84	0.063	0.81
LN Obturator Left	19	0.83	0.026	0.82
LN Obturator Right	19	0.83	0.041	0.81
LN Presacral	19	0.68	0.144	0.61
Penile Bulb	30	0.74	0.092	0.71
Prostate	12	0.87	0.057	0.83
Proximal Femur Left	20	0.93	0.028	0.92
Proximal Femur Right	20	0.92	0.027	0.91
Rectum	74	0.82	0.088	0.8
Seminal Vesicles	18	0.77	0.1	0.72
Sigmoid	74	0.8	0.107	0.77
Uterus	25	0.88	0.043	0.86

¹ structures with secondary guideline support added in subject device.

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Quantitative evaluation of new organs in the subject device

Two quantitative metrics (DICE & ASSD) and a qualitative clinical user evaluation were employed. Clinical user evaluation included a four-point scale to evaluate each contour in the context of time savings compared to contouring from scratch.

Our **acceptance criteria** combine the statistical tests and the user evaluation - only structures that pass two or more tests could be included in the final models:

1. Statistical non-inferiority of the Dice score compared with the reference device.
2. Statistical non-inferiority of the ASSD score compared with the reference device.
3. Average user evaluation of 3 or higher.

Non-inferiority is defined for:

DICE: such that the lower 95th percentile confidence bound of the subject device is greater than the mean reference performance subtracted by a 10% margin.

ASSD: such that the upper 95th percentile confidence bound of the subject device is smaller than the mean reference performance added by the standard deviation.

Test result: Passed for all new organs. The quantitative performance is shown in the table below.

<i>Structure</i>	<i># Test Cases</i>	<i>DICE</i>			<i>ASSD (mm)</i>		
		<i>Mean</i>	<i>Std.Dev</i>	<i>Lower 95th % Confidence Interval</i>	<i>Mean</i>	<i>Std.Dev</i>	<i>Upper 95th % Confidence Interval</i>
Lacrimal Gland Left	66	0.7	0.069	0.69	0.85	0.255	0.92
Lacrimal Gland Right	66	0.68	0.112	0.66	1	0.612	1.15
Pituitary Gland	66	0.73	0.095	0.71	0.76	0.39	0.85
Humeral Head Left	70	0.94	0.019	0.94	0.7	0.319	0.78
Humeral Head Right	70	0.94	0.025	0.94	0.74	0.418	0.84

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Structure	# Test Cases	DICE			ASSD (mm)		
		Mean	Std.Dev	Lower 95th % Confidence Interval	Mean	Std.Dev	Upper 95th % Confidence Interval
N2 Station 1: Highest Mediastinal Nodes Left	59	0.7	0.1	0.67	2.34	1.013	2.6
N2 Station 1: Highest Mediastinal Nodes Right	59	0.67	0.108	0.64	2.36	0.784	2.56
N2 Station 2: Upper Paratracheal Nodes Left	59	0.67	0.072	0.65	1.43	0.445	1.54
N2 Station 2: Upper Paratracheal Nodes Right	59	0.51	0.146	0.47	2.58	1.541	2.98
N2 Station 3A: Prevascular Nodes	59	0.75	0.072	0.73	1.58	0.393	1.68
N2 Station 3P: Retrotracheal Nodes	59	0.66	0.057	0.65	1.53	0.575	1.68
N2 Station 4: Lower Paratracheal Nodes Left	59	0.6	0.114	0.58	1.8	0.998	2.06
N2 Station 4: Lower Paratracheal Nodes Right	59	0.71	0.086	0.69	1.72	0.724	1.91
N2 Station 5: Subaortic Nodes	59	0.59	0.146	0.55	1.84	0.921	2.08
N2 Station 6: Para-aortic Nodes	59	0.58	0.143	0.54	1.98	1.089	2.26
N2 Station 7: SubCarinal Nodes	59	0.6	0.064	0.58	1.78	0.719	1.97
N2 Station 8: Paraesophageal Nodes	59	0.67	0.071	0.65	1.83	0.766	2.03
N2 Station 9: Pulmonary Ligament Nodes Left	59	0.39	0.169	0.35	4.28	3.417	5.17
N2 Station 9: Pulmonary Ligament Nodes Right	57	0.4	0.147	0.36	3.3	1.758	3.76
N1 Station 10: Hilar Nodes Left	59	0.55	0.095	0.52	1.19	0.666	1.37
N1 Station 10: Hilar Nodes Right	59	0.52	0.09	0.49	1.27	0.584	1.42

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<i>Structure</i>	<i># Test Cases</i>	<i>DICE</i>			<i>ASSD (mm)</i>		
		<i>Mean</i>	<i>Std.Dev</i>	<i>Lower 95th % Confidence Interval</i>	<i>Mean</i>	<i>Std.Dev</i>	<i>Upper 95th % Confidence Interval</i>
CA Left Circumflex (LCX)	63	0.28	0.125	0.25	3.81	1.427	4.17
CA Right Coronary Artery (RCA)	60	0.27	0.119	0.24	4.58	2.215	5.15
Bowel Bag	51	0.95	0.033	0.94	2.31	2.153	2.92
Femoral Head Left	59	0.95	0.011	0.95	0.55	0.144	0.59
Femoral Head Right	59	0.95	0.03	0.94	0.64	0.484	0.77
Hip Bone Left	65	0.94	0.017	0.94	0.46	0.164	0.5
Hip Bone Right	65	0.95	0.016	0.95	0.4	0.151	0.44
Sacrum	65	0.92	0.032	0.92	0.58	0.417	0.69

Subgroup analysis for photon-counting CT

Subgroup analysis was performed to evaluate the performance in terms of various CT image contrasts (achieved by varying the energy of virtual monoenergetic images derived from photon-counting CT in the energy range of conventional CT with 80 kVp to 140 kVp) and image resolutions (achieved by varying the sharpness of reconstruction kernels) with respect to reference settings using the following subgroups:

- Image contrast: Six different virtual monoenergetic images (VMIs) from 50 keV to 100 keV in 10 keV steps with smooth image impression (Qr40)
- Image resolution: Four different sharpness levels of reconstruction kernels from soft (Qr32) to sharp (Qr76)

Evaluation cohort:

- 199 oncological patient cases with and without metal implants

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- 326 CT acquisitions in total covering various body regions in different phases after iodine contrast injection (early arterial, late arterial, venous, late venous, delayed) or without contrast injection

Robustness assessment:

- Reference image contrast and resolution for generating the reference organ contour with the subject device: 70 keV VMI with Qr40 (similar image impression as conventional CT with 120 kVp [1-4])
- Robustness assessment with respect to possible conventional image contrasts [1-5]
 - o 80 kVp (equal to 58 keV VMI)
 - o 120 kVp (equal to 70/71 keV VMI)
 - o 140 kVp (equal to 79 keV VMI)
 simulated by VMIs with 50 keV, 60 keV, 70 keV, 80 keV, 90 keV, 100 keV derived from photon-counting CT.
- Robustness assessment with respect to possible image sharpness levels from soft to sharp: Qr32, Qr40, Qr60, Qr76.

The mean and standard deviation of Dice coefficients (between reference and variable image impression), along with the lower 95th percentile confidence bound, were calculated for structures obtained by the subject device.

The **acceptance criterion** for segmentation robustness is fulfilled when the mean Dice is greater or equal to the reference mean Dice.

Test Result: All organs evaluated passed the acceptance criterion. Robustness assessment of structures for different image contrasts and image resolutions, grouped by body region are shown in the tables below.

<i>Body Region</i>	<i>Robustness assessment of structures/OAR for different image contrasts</i>	
	<i>#Images</i>	<i>DICE</i>

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		<i>Mean</i>	<i>Std. Dev</i>	<i>Lower 95th % Confidence Interval</i>
Abdomen	16572	0.97	0.076	0.89
Body	8390	0.97	0.032	0.93
Cardiac	6692	0.95	0.074	0.78
Head and Neck	21019	0.90	0.143	0.67
Pelvis	19960	0.93	0.123	0.76
Thorax	74624	0.95	0.080	0.86

<i>Body Region</i>	<i>Robustness assessment of structures for different image resolutions</i>			
	<i>#Images</i>	<i>DICE</i>		
		<i>Mean</i>	<i>Std. Dev</i>	<i>Lower 95th % Confidence Interval</i>
Abdomen	9975	0.99	0.039	0.96
Body	5034	0.99	0.012	0.97
Cardiac	4017	0.98	0.038	0.93
Head and Neck	12770	0.93	0.117	0.80
Pelvis	12114	0.98	0.066	0.92

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Thorax	44819	0.98	0.039	0.94
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MR auto-contouring of brain metastasis

The AI-based auto-contouring feature of *syngo.via* RT Image Suite was tested on 30 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 MR scanners and typical magnetic field strengths. The test data covers:

- Regional distribution
- Demographic distribution: Male/female
- Distribution by manufacturer of the scanner: GE, Siemens

Subgroup analysis regarding manufacturer and gender did not show any confounder.

Distribution of test data across subgroups for MR auto-contouring of brain metastasis

Subgroup	# Test data sets
Data Source	USA: 11 EU:30 Unknown: 19
Body Region	Intraparenchymal brain: 60
Sequence	MR T1W Post-contrast
Gender	Male: 24 female: 17, Unknown: 19
Age	[<30Y]: 3 [30Y – 50Y]: 16 [50Y – 60Y]: 10 [60Y – 70Y]: 17 [>70Y]: 14
Field strength	1.5T: 48 3.0 T: 12

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Subgroup	# Test data sets
Manufacturer	Siemens: 33, GE: 27

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. Analysis was performed on Hausdorff Distance, DICE (Dice Similarity Coefficient), false-positive rate/case and sensitivity. Performances from an FDA cleared device were used as reference standard.

Quantitative evaluation of MR auto-contouring for Brain Metastases

Our **acceptance criteria** involve the following statistical tests - only structures that pass both the quantitative metrics are included in the final models:

1. Statistical non-inferiority of the Lesionwise DICE compared with the reference device.
2. Statistical non-inferiority of the Lesionwise Sensitivity compared with the reference device.

Non-inferiority is defined for.

Lesionwise DICE: such that the lower 95th percentile confidence bound of the subject device is greater than the mean reference dice coefficient subtracted by a 10% margin.

Lesionwise Sensitivity: such that the lower 95th percentile confidence bound of the subject device is greater than the mean reference sensitivity subtracted by a 10% margin.

Test result: *Passed*. Performance results are shown in the table below.

		<i>DICE</i>	<i>Sensitivity (%)</i>
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<i>Structure</i>	<i># Test Cases</i>	<i>Mean</i>	<i>Std.Dev</i>	<i>Lower 95th % Confidence Interval</i>	<i>Mean</i>	<i>Std.Dev</i>	<i>Lower 95th % Confidence Interval</i>
Brain metastases (parenchymal)	60	0.74	0.17	0.72	92.5	3.4	85.8

MR auto-contouring of brain OAR

The AI-based auto-contouring feature of *syngo.via* RT Image Suite was tested on 81 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 MR scanners and typical magnetic field strengths. The test data covers:

- Regional distribution (North America: US;)
- Demographic distribution: Male/female
- Distribution by manufacturer of the scanner: GE, Siemens
- Distribution of different field strengths: 1.5 and 3T

Subgroup analysis regarding manufacturer, field strength and gender did not show any confounder.

Distribution of test data across subgroups for MR auto-contouring of brain OAR

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Subgroup	# Test data sets
Data Source	USA: 26, EU: 35, Unknown: 20
Body Region	brain: 81
Sequence	MR T1W Post-contrast
Gender	Male: 30, female: 31, Unknown: 20
Age	[<30Y]: 1 [30Y – 50Y]: 17 [50Y – 60Y]: 15 [60Y – 70Y]: 18 [>70Y]: 20 Unknown: 10
Field strength	1.5T: 61, 3T: 20
Manufacturer	Siemens: 50, GE: 31

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. Analysis was performed on DICE (Dice Similarity Coefficient) and ASSD (Average symmetric surface distance). Performances from the FDA cleared devices were used as the reference standard

MR auto-contouring of pelvis OAR

The AI-based auto-contouring feature of *syngo.via* RT Image Suite was tested on 153 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 MR scanners and typical magnetic field strength. The test data covers:

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- Regional distribution (North America: US; Europe: Germany, Romania, France, Switzerland, Spain; Australia)
 - Distribution by manufacturer of the scanner: GE, Siemens, Philips
 - Distribution of different field strengths: 1.5 and 3T
- Subgroup analysis regarding manufacturer, field strength did not show any confounder.

Distribution of test data across subgroups for MR auto-contouring of pelvis OAR

Subgroup	# Test data sets
Data Source	US (4 sites): 78; Europe (7 sites): 75; Australia (1 site): 1
Body Region	Male pelvis: 153
Sequence	T2 W TSE, T1 VIBEDixon W
Gender	Male: 154
Age	[40Y – 50Y]: 11 [50Y – 60Y]: 8 [60Y – 70Y]: 35 [70Y – 80Y]: 31 > 80Y: 2 Unknown: 66
Field strength	1.5T: 51, 3T: 102
Manufacturer	Siemens: 66, GE: 18, Philips: 69

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. Analysis was performed on DICE (Dice Similarity Coefficient) and ASSD (Average symmetric surface distance). Performances from the FDA cleared devices were used as the reference standard.

Quantitative evaluation of MR auto-contouring for Brain and Pelvis OARs

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The **acceptance criteria** combine the statistical tests and a qualitative clinical user evaluation. (Clinical user evaluation included a four-point scale to evaluate each contour in the context of time savings compared to contouring from scratch) - only structures that pass two or more tests could be included in the final models:

1. Statistical non-inferiority of the DICE score compared with the reference device.
2. Statistical non-inferiority of the ASSD score compared with the reference device.
3. Average user evaluation of 3 or higher.

Non-inferiority is defined for

DICE: such that the lower 95th percentile confidence bound of the subject device is greater than the mean reference performance subtracted by a 10% margin.

ASSD: such that the upper 95th percentile confidence bound of the subject device is smaller than the mean reference performance added by the standard deviation.

Test result: Passed for all organs. Quantitative performance results for both Brain and Pelvis OARs are shown in the tables below.

<i>Structure (Brain OAR)</i>	<i># Test Cases</i>	<i>DICE</i>			<i>ASSD (mm)</i>		
		<i>Mean</i>	<i>Std.Dev</i>	<i>Lower 95th % Confidence Interval</i>	<i>Mean</i>	<i>Std.Dev</i>	<i>Upper 95th % Confidence Interval</i>
Brainstem	81	0.93	0.02	0.92	0.54	0.15	0.57
Cochlea Left	80	0.5	0.18	0.46	1.11	0.84	1.3
Cochlea Right	81	0.49	0.19	0.45	1.07	0.76	1.23
Cornea Left	81	0.52	0.16	0.48	0.59	0.35	0.66
Cornea Right	81	0.53	0.15	0.5	0.66	0.8	0.83

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Eye Left	79	0.92	0.05	0.9	0.4	0.24	0.45
Eye Right	79	0.92	0.03	0.92	0.36	0.15	0.4
Hippocampus Left	81	0.77	0.07	0.75	0.72	0.36	0.79
Hippocampus Right	81	0.76	0.08	0.75	0.71	0.31	0.77
Lacrimal Gland Left	80	0.56	0.2	0.51	1.6	1.58	1.95
Lacrimal Gland Right	81	0.57	0.2	0.52	1.48	1.3	1.77
Lens Left	77	0.75	0.14	0.71	0.43	0.3	0.5
Lens Right	76	0.77	0.15	0.73	0.42	0.36	0.5
Optic Chiasm	81	0.66	0.11	0.63	0.69	0.66	0.84
Optic Nerve Left	81	0.54	0.15	0.51	1.21	2.7	1.8
Optic Nerve Right	81	0.57	0.14	0.54	0.85	0.86	1.04
Pituitary Gland	79	0.65	0.17	0.61	0.76	0.47	0.86
Retina Left	81	0.62	0.15	0.59	0.43	0.5	0.54
Retina Right	81	0.63	0.11	0.6	0.38	0.14	0.4
Spinal cord	80	0.86	0.09	0.84	0.51	0.47	0.61

Structure (Pelvis OAR)	# Test Cases	DICE			ASSD (mm)		
		Mean	Std.Dev	Lower 95th % Confidence Interval	Mean	Std.Dev	Upper 95th % Confidence Interval
T1 Pelvis							
Body	55	0.98	0.01	0.98	1.4	1.56	1.82
Femur head Left	55	0.93	0.03	0.92	1.1	0.59	1.26
Femur head Right	55	0.94	0.02	0.93	0.96	0.48	1.09

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T2 Pelvis							
Anus	98	0.73	0.1	0.71	2.24	1.16	2.47
Bladder	98	0.9	0.08	0.88	1.36	0.85	1.53
Penile Bulb	95	0.81	0.09	0.79	0.91	0.76	1.07
Prostate	90	0.86	0.07	0.84	1.66	2.01	2.08
Rectum	98	0.86	0.06	0.85	1.92	2.01	2.32
Seminal Vesicles	89	0.72	0.14	0.69	1.78	1.25	2.05

Synthetic CT for pelvis and brain

The AI-based synthetic CT feature of *syngo.via* RT Image Suite was tested on 51 subjects. The test data was generated from an independent set that was not seen by the model during training stage to cover a range of MR scanners and typical magnetic field strengths. The test data covers:

- Regional distribution (North America, Europe)
- Distribution of different field strengths: 1.5 and 3T
- Distribution of different Siemens scanners

Distribution of test data across subgroups for synthetic CT

Subgroup	# Test data sets
Data Source	US: 17; Europe: 18; Unknown: 16
Body Region	pelvis: 29, brain: 22
Sequence	T1 VIBE Dixon
Gender	Male: 24, female: 21, unknown: 6

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Subgroup	# Test data sets
Age	[21Y-40Y]:6 [41Y-60Y]:11 [61Y-80Y]:18 Unknown:16
Field strength	1.5T: 33, 3T: 18
Siemens scanners	MAGNETOM Aera: 24, MAGNETOM Skyra: 5, MAGNETOM Vida: 13, MAGNETOM Sola: 1, MAGNETOM Sola Fit: 1

The testing ensures the quantitative performance of the resulting synthetic CT. Analysis was performed on geometric fidelity and HU accuracy.

Semi-automated isocenter estimates of vertebrae (cleared in K220450)

The AI-based algorithm is cleared within the medical device *syngo*.CT Applications (K220450, clearance date 03/7/2022). It was tested on 426 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 test data covers:

- Regional distribution (North America: US; Asia: CN, IN, CO; Europe: BE, CH, F, UK, DE)
- Demographic distribution: Male/female
- Distribution by manufacturer of the scanner: GE, Siemens, Philips, Toshiba, NeuroLogica

Distribution of test data across subgroups for *Semi-automated isocenter estimates or defining isocenters via RTP lasers*

Subgroup	# Test data sets
Data Source	Europe: 142, US: 126, Asia: 131, unknown: 27
Body Region	Head&Neck: 113, Thorax&Abdomen: 264, Pelvis: 92
Gender	Male: 187, female: 74, Unknown: 165

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Age	[0-2]:5 , [3-12]: 25, [13-19]: 64, [20-29]:38 [30-39]:21 [40-49]:71 [50-59]:46 [60-69]:80 [70-79]:49 [80-89]:12 unknown: 15
Slice thickness (in mm)	<=1:20, (1,2]: 220, (2,3]: 209, >3: 20
Manufacturer	Siemens: 369, GE: 10, Philips: 28, Toshiba: 2; NeuoLogica: 14 unknown/others: 3

Manual ground-truth of spine landmarks were annotated by an expert team, followed by a rigorous independent quality assessment. The testing ensures the quantitative performance of the resulting landmarks by comparing them to the manually annotated ground truth. Analysis was performed on percentage of cases which need corrections.

VIII. Use of Consensus Standards:

The following list of FDA-recognized, voluntary consensus standards were utilized in the design and evaluation of the subject device's safety and efficacy.

Standard Organization	Title
ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Information supplied by the manufacturer of medical devices
IEC 62304:2006 + A1:2016	Medical Device Software - Software Lifecycle processes

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IEC 62366-1:2015+A1:2020	Application of Usability Engineering to Medical Devices
IEC 82304-1:2016	Health software Part 1: General requirements for product safety
IEC 61217:2011	Radiotherapy Equipment, Coordinates, Movements and Scales
IEC 62083:2009	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems
UL ANSI 2900-1:2017	Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
UL ANSI 2900-2-1:2017	Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
IEC 81001-5-1:2021	Health Software and Health IT Systems Safety, Effectiveness and Security - Part 5-1: Security - Activities In The Product Life Cycle

IX. Determination of Substantial Equivalence to the Predicate

A subset of software features and characteristics of the subject device are different from the predicate device. However, Siemens Healthineers considers these differences to be enhancements of the predicate. The principle of operation of the subject device is the same as that of the existing predicate device. Verification and validation demonstrate that the subject device is as safe, as effective as the predicate. VBrain serves as a reference device within this submission. *syngo.via* RT Image Suite VC10 is comparable to VBrain (K203235) and has similar performance

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metrics with respect to the ability to contour metastases in MR images. Siemens Healthineers therefore believes that the subject device is substantially equivalent to the predicate device.