July 10, 2026

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

Re: K261306
Trade/Device Name: AI Contouring (VA10A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: April 20, 2026
Received: April 20, 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261306

Please provide the device trade name(s).

AI Contouring (VA10A)

Please provide your Indications for Use below.

AI Contouring is a post-processing software intended to automatically contour CT and MR structures, including known (diagnosed) brain metastases, using deep-learning-based algorithms.
Contours that are generated by AI Contouring may be used as input for clinical workflows for radiation therapy treatment planning. AI Contouring must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI Contouring. The outputs of AI Contouring are intended to be used by qualified and trained medical professionals.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Premarket Notification - 510(k) Summary

Traditional 510(k) Submission for AI Contouring (VA10A)

I. Submitter's Name

Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304
Contact Name: Lynn, Allman, PhD., Senior Director Regulatory Affairs
Phone: (650) 424-5369
E-mail: submissions.support@varian.com
Date Prepared: April 20, 2026

II. Device Information

Proprietary Name: AI Contouring (VA10A)
Classification Name: Medical image management and processing system
Regulation Number: §892.2050
Product Code: QKB

III. Predicate Device

AI Rad Companion Organs RT (K242745)

Reference Device: syngo.via RT Image Suite (VC10) (K252304)

IV. Device Description

The AI Contouring VA10A software is intended for use in the automatic segmentation (autocontouring) of anatomical structures and pathologies on CT and MR images to support radiation therapy treatment planning. It is designed to assist clinicians by providing consistent, editable contours of organs at risk (OARs) and target volumes, streamlining the radiotherapy planning workflow.

The AI Contouring VA10A system consists of the following components:

- A software engine integrated into compatible Varian medical device platforms (e.g., Eclipse, Velocity)
- Version-controlled AI Contouring software modules for CT and MR image segmentation
- Four independent deep learning-based segmentation models for MR images
- Multiple deep image-to-image network (DI2IN) models for CT-based segmentation

The primary purpose of the system is to receive a data-stream from partner medical devices (Eclipse Treatment Planning System and Velocity) consisting of a voxel stream generated out of medical image files, compute structure sets representing anatomical structures that are specified by the configured template and return those results to the partner medical device as a voxel stream. The application includes capabilities and functionalities to support:

- Auto contouring of anatomical structures and known (diagnosed) brain metastases
- Template configuration

- Expansion of auto-contoured structures including
  - Margin
  - Boolean
  - Cropping operations

The AI Contouring is a modular, deep learning-based system that includes:

- **CT Autocontouring Module**: Uses anatomical landmark detection and DI2IN segmentation to identify and contour structures in CT images.
- **MR Autocontouring Module**: Includes four independent models for:
  - Brain Metastases (T1wPost MR)
  - Brain Organs at Risk (OARs)
  - Pelvis OARs (T1-weighted)
  - Pelvis OARs (T2-weighted)

Each model is trained on large, diverse datasets and optimized for high accuracy and generalizability across imaging modalities and patient demographics. The subject device additionally supports contouring known (diagnosed) brain metastasis.

V. Indications for Use

AI Contouring is a post-processing software intended to automatically contour CT and MR structures, including known (diagnosed) brain metastases, using deep-learning-based algorithms.

Contours that are generated by AI Contouring may be used as input for clinical workflows for radiation therapy treatment planning. AI Contouring must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring applications, to review, edit, and accept contours generated by AI Contouring.
The outputs of AI Contouring are intended to be used by qualified and trained medical professionals.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1: Comparison of Technological Characteristics with the Predicate Device

Feature	Predicate Device: AI-Rad Companion Organs RT (K242745)	Subject Device: AI Contouring VA10A	Comparison
Intended Use	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep learning algorithms.	AI Contouring is a post-processing software intended to automatically contour CT and MR structures using deep-learning-based algorithms.	The subject device and predicate device share a similar intended use. Both devices are intended for automated contouring of CT and MR structures for radiation therapy treatment planning. The subject device additionally supports contouring known (diagnosed) brain metastasis. The subject device additionally supports
Indications for Use	AI-Rad Companion Organs RT is a post-processing software intended to automatically contour DICOM CT and MR pre-defined structures using deep-learning-based algorithms. Contours that are generated by AI-Rad Companion Organs RT may be used as input for clinical workflows including external beam radiation therapy treatment planning. AI-Rad Companion Organs RT must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive	AI Contouring is a post-processing software intended to automatically contour CT and MR structures, including known (diagnosed) brain metastases, using deep-learning-based algorithms. Contours that are generated by AI Contouring may be used as input for clinical workflows for radiation therapy treatment planning. AI Contouring must be used in conjunction with appropriate software such as Treatment Planning Systems and Interactive Contouring	

	Contouring applications, to review, edit, and accept contours generated by AI-Rad Companion Organs RT. The outputs of AI-Rad Companion Organs RT are intended to be used by trained medical professionals. The software is not intended to automatically detect or contour lesions.	applications, to review, edit, and accept contours generated by AI Contouring. The outputs of AI Contouring are intended to be used by qualified and trained medical professionals.	contouring known (diagnosed) brain metastasis
Contraindications for Use	The intended patient population is not subject to any restrictions. However, automated contouring works best with adult patients.	The intended patient population is not subject to any restrictions. However, automated contouring works best with adult patients.	Same as predicate
Environment	Professional healthcare facilities	Professional healthcare facilities. The device is designed to be used in conjunction with a partner medical device on a workstation or a user provided computational environment to perform automated contouring in the radiation therapy context. The partner medical device provides DICOM medical image viewing and annotation capabilities, while AI contouring only processes images to create contours.	Substantially equivalent
Type of Users	Qualified healthcare professionals	Qualified healthcare professionals	Same as predicate

The modified device, referred to as the "subject device" throughout this summary, is release version VA10A of the AI Contouring.

At a high level, both the predicate device and the subject device are based on the same characteristics:

- Both the subject device and the predicate are software tools used to automatically contour CT and MR structures
- They are computer-based software devices used by trained medical professionals with treatment planning systems
- The outputted contours by both devices are used as input for clinical workflows for radiation therapy treatment planning

AI Contouring contains a subset of features from the predicate and reference device. Below compares the Advanced Contouring feature against the predicate and reference device. The reference device, syngo.via RTiS VC10, is used to establish methods and test criteria to help establish substantial equivalence for AI Contouring. syngo.via RTiS VC10 is not used as a predicate device but serves to establish the acceptability of analytical and statistical methodologies, including segmentation accuracy metrics (e.g., Dice and ASSD) and non-inferiority testing frameworks. Given that AI Contouring employs the same underlying deep learning technology and derives from comparable datasets and validated algorithms, the use of syngo.via RTiS VC10 provides a scientifically justified benchmark for performance evaluation.

Table 2: Comparing Advanced Contouring between the subject and predicate/reference device

Feature	Similarities	Differences in AI Contouring	Impact assessment

Advanced Contouring	The underlying deep learning technology for this extension is unchanged. It reuses the same technology.	AI Contouring does not include manual or adaptive contouring tools, but auto-contouring tools are substantially equivalent to AI Rad Companion and a subset of tools present in Syngo.Via RT Image Suite.	While AI Contouring is a distinct medical device from the predicate and reference devices, it re-uses the algorithms and technology from the predicate and reference devices with no changes.

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 enhanced 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."

Human Factors and Usability testing was conducted and documentation was provided as recommended in FDA's guidance document "Applying Human Factors and Usability Engineering to Medical Devices (Feb 2016)."

Cybersecurity and Interoperability requirements were assessed per FDA guidance's "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (Feb 2026)", "Postmarket Management of Cybersecurity in Medical Devices (Jan 2016)", "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices (Jan 2016)".

Testing of AI Contouring followed a multi-level test approach, through unit, integration, and system (end-to-end) level testing. Software design verification and design validation testing was performed according to the FDA Quality System Regulation (21 CFR §820), ISO 13485 Quality Management System Standard, ISO 14971 Risk Management Standard, and IEC 62304 Software Life Cycle Process standard. Test results demonstrate conformance to applicable requirements specifications and assure hazard safeguards function properly. Software design verification and design validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (June 2023).

Test results demonstrate conformance to applicable requirements and specifications.
No animal studies have been included in this pre-market submission.

VIII. Summary of Clinical Validation

Mitigating Bias and Improving Generalizability
For training and validation of the algorithm, data was considered from different regions, such as North and South America, Asia, Australia, and Europe. This data provided a large variability in age, gender, geographic origin, and so forth. In addition, RT data acquired with different hardware and image settings was considered, for example, multiple CT or MR scanner vendors, and different slice thickness. The characteristics (for example, size and diversity) of both the data sets were chosen to achieve a reliable model that is robust against potential bias.

Imaging Equipment

For CT imaging data, AI Contouring has been tested and validated on multi-vendor data sets, including Siemens Healthineers, GE, and Philips scanners.
For MR Pelvic OAR (organ at risk), AI Contouring has been tested and validated on data sets from Siemens Healthineers, Philips, and GE scanners for T1w image series.
For MR Brain OAR and MR Brain Metastases, AI Contouring has been tested on data sets from Siemens Healthineers and GE scanners.

Training Data
The performance of the AI Contouring algorithm has been evaluated for several clinically relevant subgroups. However, as the number of available patients was very limited, no analysis was conducted for the subgroup of CT images with/without contrast medium; and the subgroup of MR brain metastases with different field strengths.

CT AI Contouring: The composition of the CT training data (in cases where patient age was available) predominantly consisted of patients in the age group of 50−70 and those older than 70 years. While this is appropriate to the intended patient population for radiotherapy, there was a relatively small proportion of testing and training data representing patients below the age of 50. This indicates that a more careful review for this age group may be necessary.

CT AI Contouring on photon counting CT or multi-energy CT: Monoenergetic scans or virtual monoenergetic images (VMI) are recommended. Performance was evaluated using patient cases acquired with the NAEOTOM Alpha class using varying energies such as virtual monoenergetic images (VMIs) and convolution kernels (soft to sharp). The VMIs were evaluated between 50 keV and 100 keV, which cover the image contrasts achievable with a conventional X-ray spectrum between 80 kVp and 140 kVp.

MR AI Contouring: The training data for MR pelvis AI Contouring comprised noncontrast enhanced images of the male pelvis, with magnetic field strengths of 1.5 T and 3 T, and excluded prostatectomy cases. The training data for MR brain AI Contouring comprised contrast-enhanced MR images, with magnetic field strengths of 1.5 T and 3 T. The training data for the MR brain metastases algorithm comprised of intraparenchymal metastases of at least 2 mm in each dimension and not adjacent to a surgical bed, with images acquired preradiation therapy.

MR AI Contouring for brain metastases: Software is not intended to be used for diagnostic purposes. In case of additionally found metastases (compared to the diagnostic information), the physician/ radiologist shall perform a review.

Subgroup Analysis
CT Imaging
Subgroup analysis was performed to evaluate the performance in terms of average Dice according to the following subgroups:
- Manufacturer of the planning CT system: Siemens, GE, Philips
- Slice thickness: <= 1 mm, (1-2] mm, (2-3] mm, > 3 mm
- Gender: Male or Female

No notable variation between the subgroups was detected.

MR Imaging
Subgroup analysis was performed to evaluate the performance in terms of average Dice according to

the following subgroups:

- Manufacturer of the MR system:
  - Brain OAR and Metastases: Siemens, GE
  - Pelvis OAR: Siemens, GE, Philips
- Magnetic Field Strength of the MR System: 1.5 Tesla or 3.0 Tesla
- Gender: Male or Female.

No notable variation between the subgroups was detected.

Algorithm Evaluation

The CT AI Contouring algorithm was tested on 469 subjects. The MR AI Contouring algorithm was tested on 153 subjects for pelvis OARs, 81 subjects for brain OARs, and 60 subjects for brain metastases. The data of the test cohort was randomly selected and was completely independent from the training and validation data.

A quantitative evaluation was performed in the form of fully automated bench tests that ensured the quantitative quality of the algorithm results by comparing them with a manually annotated ground truth.

Table 3: Distribution of test data across subgroups for CT auto-contouring

Subgroup	# Test data sets
Data Source	Europe: 107, US: 142, Canada: 16, South America: 83, Australia: 29, Asia: 33, Unknown: 13
Body Region	Head&Neck: 113, Thorax&Abdomen: 254, Pelvis: 92
Gender	Male: 200, female: 218, Unknown: 51
Age	<=30: 1 [30-50]: 6 [50;70]: 46 >70: 21 Unknown: 395
Slice thickness (in mm)	<=1:20 (1,2]: 220 (2,3]: 209 >3: 20
Manufacturer	Siemens: 148, GE: 90, Philips: 147, unknown/others: 81

Table 4: Distribution of test data across subgroups for MR auto-contouring of brain metastasis

Subgroup	# Test data sets
Data Source	US: 11, Europe: 49, Unknown: 19
Body Region	Intraparenchymal Brain
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
Slice Thickness	<1mm: 1 1mm: 40 1.2 mm: 15

	2.0mm: 3 2.2 mm: 1
Field Strength	1.5T: 48, 3.0T: 12
Manufacturer	Siemens: 33, GE: 27

Table 5: Distribution of test data across subgroups for MR auto-contouring of brain OAR

Subgroup	# Test data sets
Data Source	USA: 26, EU: 35, Unknown: 20
Body Region	Brain Organs at Risk (OARs)
Sequence	MR T1W Post-contrast
Gender	Male: 8, female: 18, Unknown: 20
Age	[<30Y]: 1 [30Y – 50Y]: 17 [50Y – 60Y]: 15 [60Y – 70Y]: 18 [>70Y]: 20 Unknown: 10
Slice Thickness	<1mm: 5 1mm: 55 1.1mm:3 1.2 mm: 13 1.4mm: 1 2.0mm: 3 2.2 mm: 1
Field strength	1.5T: 61, 3.0T: 20
Manufacturer	Siemens: 50, GE: 31

Table 6: 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 Organs at Risk
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
Slice Thickness	<4mm
Field strength	1.5T: 51, 3T: 102
Manufacturer	Siemens: 66, GE: 18, Philips: 69

Study Results

CT Contouring

The algorithm was evaluated on 469 subjects. The description of the test data can be split into two cohorts A and B. The data of both cohorts were randomly selected and are completely independent from the training and validation data. Cohort A corresponds to the test cohort of 413 patients used in the

predicate device. Cohort B was newly introduced in the subject device and contains image data of an additional 56 patients. The reference device for the 'Reference Standard' is syngo.via RTiS VC10.

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. Average user evaluation of 3 or higher, when measured on a four-point scale.

AI Contouring reuses the same deep learning algorithms and code base as syngo.via RTiS, with identical technological characteristics and no modifications to the underlying autocontouring functionality. As a result, the scientific methodologies and performance metrics previously applied and accepted for syngo.via RTiS remain applicable to the subject device.

Table 7: Quantitative evaluation results of DICE for new organs in subject device

Structure	***Reference Standard: syngo.via RTiS VC10***	***Subject Device***			***Equivalence Shown***
	DICE Mean±Std.Dev	***DICE Mean***	***DICE Std.Dev***	***Lower 95th % Confidence Interval***	
Lacrimal Gland Left	0.72±0.073	0.7	0.069	0.69	Yes
Lacrimal Gland Right	0.699±0.123	0.68	0.112	0.66	Yes
Pituitary Gland	0.758±0.074	0.73	0.095	0.71	Yes
Humeral Head Left	0.942±0.021	0.94	0.019	0.94	Yes
Humeral Head Right	0.946±0.032	0.94	0.025	0.94	Yes
N2 Station 1: Highest Mediastinal Nodes Left	0.707±0.1	0.7	0.1	0.67	Yes
N2 Station 1: Highest Mediastinal Nodes Right	0.66±0.128	0.67	0.108	0.64	Yes
N2 Station 2: Upper Paratracheal Nodes Left	0.676±0.076	0.67	0.072	0.65	Yes
N2 Station 2: Upper Paratracheal Nodes Right	0.555±0.136	0.51	0.146	0.47	Yes
N2 Station 3A: Prevascular Nodes	0.756±0.063	0.75	0.072	0.73	Yes
N2 Station 3P: Retrotracheal Nodes	0.659±0.06	0.66	0.057	0.65	Yes
N2 Station 4: Lower Paratracheal Nodes Left	0.657±0.084	0.6	0.114	0.58	Yes
N2 Station 4: Lower Paratracheal Nodes Right	0.728±0.08	0.71	0.086	0.69	Yes
N2 Station 5: Subaortic Nodes	0.61±0.148	0.59	0.146	0.55	Yes
N2 Station 6: Para-aortic Nodes	0.588±0.148	0.58	0.143	0.54	Yes
N2 Station 7: SubCarinal Nodes	0.59±0.076	0.6	0.064	0.58	Yes
N2 Station 8: Paraesophageal Nodes	0.658±0.08	0.67	0.071	0.65	Yes

N2 Station 9: Pulmonary Ligament Nodes Left	0.383±0.211	0.39	0.169	0.35	Yes
N2 Station 9: Pulmonary Ligament Nodes Right	0.388±0.156	0.4	0.147	0.36	Yes
N1 Station 10: Hilar Nodes Left	0.529±0.097	0.55	0.095	0.52	Yes
N1 Station 10: Hilar Nodes Right	0.502±0.095	0.52	0.09	0.49	Yes
CA Left Circumflex (LCX)	0.312	0.28	0.125	0.25	Yes
CA Right Coronary Artery (RCA)	0.38	0.27	0.119	0.24	No
Bowel Bag	0.95±0.036	0.95	0.033	0.94	Yes
Femoral Head Left	0.952±0.011	0.95	0.011	0.95	Yes
Femoral Head Right	0.949±0.013	0.95	0.03	0.94	Yes
Hip Bone Left	0.934±0.016	0.94	0.017	0.94	Yes
Hip Bone Right	0.939±0.013	0.95	0.016	0.95	Yes
Sacrum	0.907±0.04	0.92	0.032	0.92	Yes

Table 8: Quantitative evaluation results of ASSD for new organs in subject device

Structure	***Reference Standard: syngo.via RTiS VC10***	***Subject Device***			***Equivalence Shown***
	ASSD Mean±Std.Dev	***ASSD Mean***	***ASSD Std.Dev***	***Upper 95th % Confidence Interval***	
Lacrimal Gland Left	0.8 ± 0.3	0.85	0.255	0.92	Yes
Lacrimal Gland Right	0.9 ± 0.7	1	0.612	1.15	Yes
Pituitary Gland	0.7 ± 0.3	0.76	0.39	0.85	Yes
Humeral Head Left	0.7 ± 0.3	0.7	0.319	0.78	Yes
Humeral Head Right	0.7 ± 0.5	0.74	0.418	0.84	Yes
N2 Station 1: Highest Mediastinal Nodes Left	2.4 ± 1.2	2.34	1.013	2.6	Yes
N2 Station 1: Highest Mediastinal Nodes Right	2.4 ± 0.9	2.36	0.784	2.56	Yes
N2 Station 2: Upper Paratracheal Nodes Left	1.4 ± 0.4	1.43	0.445	1.54	Yes
N2 Station 2: Upper Paratracheal Nodes Right	2.3 ± 1.5	2.58	1.541	2.98	Yes
N2 Station 3A: Prevascular Nodes	1.6 ±0.4	1.58	0.393	1.68	Yes
N2 Station 3P: Retrotracheal Nodes	1.6 ± 0.6	1.53	0.575	1.68	Yes
N2 Station 4: Lower Paratracheal Nodes Left	1.4 ± 0.7	1.8	0.998	2.06	Yes
N2 Station 4: Lower Paratracheal Nodes Right	1.7 ±0.7	1.72	0.724	1.91	Yes
N2 Station 5: Subaortic Nodes	1.8 ±0.8	1.84	0.921	2.08	Yes

N2 Station 6: Para-aortic Nodes	2 ±1.1	1.98	1.089	2.26	Yes
N2 Station 7: SubCarinal Nodes	1.9 ±0.9	1.78	0.719	1.97	Yes
N2 Station 8: Paraesophageal Nodes	2 ±0.9	1.83	0.766	2.03	Yes
N2 Station 9: Pulmonary Ligament Nodes Left	5.3 ± 4.4	4.28	3.417	5.17	Yes
N2 Station 9: Pulmonary Ligament Nodes Right	3.7 ± 2	3.3	1.758	3.76	Yes
N1 Station 10: Hilar Nodes Left	1.2 ±0.6	1.19	0.666	1.37	Yes
N1 Station 10: Hilar Nodes Right	1.4 ± 0.6	1.27	0.584	1.42	Yes
CA Left Circumflex (LCX)	4± 2.7	3.81	1.427	4.17	Yes
CA Right Coronary Artery (RCA)	5.6± 5.4	4.58	2.215	5.15	Yes
Bowel Bag	1.9± 1.5	2.31	2.153	2.92	Yes
Femoral Head Left	0.5 ± 0.2	0.55	0.144	0.59	Yes
Femoral Head Right	0.6 ± 0.2	0.64	0.484	0.77	Yes
Hip Bone Left	0.6 ± 0.2	0.46	0.164	0.5	Yes
Hip Bone Right	0.5 ± 0.1	0.4	0.151	0.44	Yes
Sacrum	0.8 ± 0.6	0.58	0.417	0.69	Yes

Table 9: Robustness assessment of structures for different image resolutions.

Structure	Reference Standard: syngo.via RTiS VC10		Subject Device			Robustness shown
	DICE		DICE			
	Mean	Std. Dev	Mean	Std. Dev	Lower 95th % Confidence Interval	
Abdominopelvic Cavity	0.93	0.032	1.00	0.012	1.00	Yes
Aorta	0.87	0.032	0.99	0.019	0.98	Yes
Atrium Left	0.86	0.048	0.99	0.005	0.99	Yes
Atrium Right	0.79	0.088	0.99	0.006	0.99	Yes
Bladder	0.95	0.050	0.99	0.018	0.96	Yes
Body	0.99	0.003	1.00	0.000	1.00	Yes
Bowel Bag	0.95	0.036	1.00	0.007	0.99	Yes
Bowel Large	0.90	0.046	0.99	0.013	0.97	Yes
Bowel Small	0.89	0.044	0.99	0.014	0.97	Yes
Brachial Plexus Left	0.63	0.086	0.94	0.062	0.89	Yes
Brachial Plexus Right	0.66	0.050	0.93	0.046	0.88	Yes
Brain	0.98	0.005	1.00	0.002	0.99	Yes
Brainstem Brouwer et al.	0.89	0.023	0.95	0.122	0.91	Yes
Brainstem DAHANCA	0.89	0.023	0.95	0.083	0.86	Yes
CA Left Anterior Descending Artery (LAD)	0.48	0.097	0.93	0.067	0.79	Yes

Chest Wall Left	0.92	0.015	1.00	0.004	0.99	Yes
Chest Wall Right	0.93	0.012	0.99	0.004	0.99	Yes
Cochlea Left	0.75	0.161	0.91	0.083	0.79	Yes
Cochlea Right	0.80	0.048	0.90	0.109	0.82	Yes
Duodenum	0.77	0.101	0.97	0.049	0.93	Yes
Esophagus DAHANCA	0.81	0.059	0.97	0.021	0.94	Yes
Esophagus RTOG	0.81	0.059	0.98	0.019	0.95	Yes
Eye Globe Left	0.89	0.037	0.98	0.014	0.96	Yes
Eye Globe Right	0.89	0.026	0.98	0.040	0.92	Yes
Female Breast Left ESTRO	0.89	0.046	0.99	0.012	0.97	Yes
Female Breast Left RTOG	0.89	0.046	0.99	0.014	0.97	Yes
Female Breast Right ESTRO	0.85	0.061	0.99	0.013	0.97	Yes
Female Breast Right RTOG	0.85	0.061	0.99	0.022	0.96	Yes
Femoral Head Left	0.95	0.011	0.99	0.009	0.99	Yes
Femoral Head Right	0.95	0.013	0.99	0.007	0.99	Yes
Glottis Brouwer et al.	0.70	0.100	0.94	0.028	0.88	Yes
Glottis DAHANCA	0.70	0.100	0.96	0.036	0.92	Yes
Heart	0.92	0.027	1.00	0.007	0.99	Yes
Hip Bone Left	0.93	0.016	0.99	0.004	0.99	Yes
Hip Bone Right	0.94	0.013	0.99	0.003	0.99	Yes
Humeral Head Left	0.94	0.021	0.99	0.012	0.99	Yes
Humeral Head Right	0.95	0.032	0.99	0.014	0.99	Yes
Kidney Left	0.93	0.018	1.00	0.006	0.99	Yes
Kidney Right	0.91	0.067	0.99	0.017	0.99	Yes
Lacrimal Gland Left	0.72	0.073	0.95	0.029	0.91	Yes
Lacrimal Gland Right	0.70	0.123	0.92	0.122	0.66	Yes
Lens Left	0.68	0.188	0.92	0.111	0.67	Yes
Lens Right	0.67	0.118	0.94	0.086	0.75	Yes
Lips	0.79	0.070	0.91	0.162	0.64	Yes
Liver	0.96	0.013	1.00	0.003	0.99	Yes
LN Axilla Level I Left	0.81	0.054	0.99	0.009	0.98	Yes
LN Axilla Level I Right	0.80	0.071	0.99	0.009	0.97	Yes
LN Axilla Level II Left	0.79	0.067	0.99	0.013	0.96	Yes
LN Axilla Level II Right	0.78	0.069	0.99	0.012	0.97	Yes
LN Axilla Level III Left	0.75	0.041	0.98	0.016	0.95	Yes
LN Axilla Level III Right	0.76	0.076	0.99	0.015	0.95	Yes
LN Common Iliac Left	0.85	0.052	0.98	0.041	0.93	Yes
LN Common Iliac Right	0.82	0.047	0.97	0.053	0.94	Yes
LN External Iliac Left	0.89	0.035	0.98	0.067	0.94	Yes
LN External Iliac Right	0.88	0.030	0.98	0.039	0.95	Yes
LN Internal Iliac Left	0.83	0.070	0.97	0.059	0.93	Yes
LN Internal Iliac Right	0.84	0.061	0.97	0.037	0.94	Yes
LN Internal Mammary Left	0.59	0.080	0.96	0.061	0.88	Yes
LN Internal Mammary Right	0.63	0.094	0.97	0.029	0.92	Yes
LN Level Ia Submental Triangle	0.64	0.156	0.92	0.107	0.82	Yes

LN Level Ib Submandibular Triangle Left	0.80	0.062	0.94	0.142	0.82	Yes
LN Level Ib Submandibular Triangle Right	0.77	0.085	0.93	0.118	0.74	Yes
LN Level II Upper Jugular Nodes Left	0.82	0.051	0.95	0.107	0.89	Yes
LN Level II Upper Jugular Nodes Right	0.80	0.062	0.94	0.135	0.87	Yes
LN Level III Middle Jugular Nodes Left	0.79	0.067	0.95	0.053	0.90	Yes
LN Level III Middle Jugular Nodes Right	0.77	0.085	0.92	0.141	0.68	Yes
LN Level IVa Lower Jugular Group Left	0.71	0.108	0.93	0.132	0.88	Yes
LN Level IVa Lower Jugular Group Right	0.73	0.084	0.90	0.180	0.63	Yes
LN Level IVb Medial Supraclavicular Group Left	0.66	0.157	0.96	0.024	0.92	Yes
LN Level IVb Medial Supraclavicular Group Right	0.70	0.109	0.96	0.026	0.90	Yes
LN Level IX Bucco-facial Group Left	0.63	0.115	0.94	0.075	0.89	Yes
LN Level IX Bucco-facial Group Right	0.60	0.123	0.94	0.060	0.86	Yes
LN Level V Posterior Triangle Group Left	0.71	0.116	0.94	0.108	0.87	Yes
LN Level V Posterior Triangle Group Right	0.69	0.121	0.94	0.058	0.80	Yes
LN Level Vc Lateral Supraclavicular Group Left	0.56	0.154	0.95	0.047	0.84	Yes
LN Level Vc Lateral Supraclavicular Group Right	0.61	0.122	0.94	0.062	0.84	Yes
LN Level VIa Anterior Jugular Nodes	0.70	0.066	0.90	0.182	0.66	Yes
LN Level VIb Prelaryngeal, Pretracheal, & Paratracheal Nodes	0.66	0.108	0.94	0.092	0.90	Yes
LN Level VIIa Retropharyngeal Nodes Left	0.53	0.100	0.85	0.170	0.47	Yes
LN Level VIIa Retropharyngeal Nodes Right	0.49	0.148	0.88	0.143	0.70	Yes
LN Level VIIb Retro-styloid Nodes Left	0.73	0.079	0.92	0.174	0.55	Yes
LN Level VIIb Retro-styloid Nodes Right	0.74	0.094	0.94	0.099	0.85	Yes
LN Level VIII Parotid Group Left	0.85	0.037	0.93	0.153	0.63	Yes

LN Level VIII Parotid Group Right	0.84	0.042	0.95	0.091	0.88	Yes
LN Level Xa Retroauricular & Subauricular Nodes Left	0.69	0.099	0.94	0.077	0.82	Yes
LN Level Xa Retroauricular & Subauricular Nodes Right	0.73	0.074	0.95	0.034	0.88	Yes
LN Level Xb Occipital Nodes Left	0.57	0.110	0.91	0.135	0.69	Yes
LN Level Xb Occipital Nodes Right	0.56	0.134	0.90	0.177	0.69	Yes
LN Obturator Left	0.83	0.026	0.98	0.036	0.94	Yes
LN Obturator Right	0.83	0.040	0.97	0.052	0.94	Yes
LN Presacral	0.68	0.140	0.97	0.031	0.92	Yes
LN Supraclavicular Left	0.79	0.083	0.99	0.014	0.96	Yes
LN Supraclavicular Right	0.80	0.067	0.99	0.016	0.96	Yes
Lung Lobe Left Lower	0.90	0.121	0.99	0.025	0.98	Yes
Lung Lobe Left Upper	0.94	0.071	1.00	0.005	0.99	Yes
Lung Lobe Right Lower	0.93	0.044	0.99	0.039	0.98	Yes
Lung Lobe Right Middle	0.89	0.077	0.98	0.078	0.90	Yes
Lung Lobe Right Upper	0.93	0.052	0.99	0.013	0.98	Yes
Mandible	0.88	0.027	0.93	0.130	0.69	Yes
N1 Station 10: Hilar Nodes Left	0.53	0.097	0.95	0.101	0.84	Yes
N1 Station 10: Hilar Nodes Right	0.50	0.095	0.95	0.098	0.82	Yes
N2 Station 1: Highest Mediastinal Nodes Left	0.71	0.100	0.97	0.062	0.92	Yes
N2 Station 1: Highest Mediastinal Nodes Right	0.66	0.128	0.97	0.067	0.90	Yes
N2 Station 2: Upper Paratracheal Nodes Left	0.68	0.076	0.95	0.121	0.85	Yes
N2 Station 2: Upper Paratracheal Nodes Right	0.56	0.136	0.96	0.067	0.89	Yes
N2 Station 3A: Prevascular Nodes	0.76	0.063	0.94	0.162	0.63	Yes
N2 Station 3P: Retrotracheal Nodes	0.66	0.060	0.93	0.156	0.54	Yes
N2 Station 4: Lower Paratracheal Nodes Left	0.66	0.084	0.96	0.074	0.89	Yes
N2 Station 4: Lower Paratracheal Nodes Right	0.73	0.080	0.97	0.088	0.90	Yes
N2 Station 5: Subaortic Nodes	0.61	0.148	0.97	0.041	0.91	Yes
N2 Station 6: Para-aortic Nodes	0.59	0.148	0.97	0.034	0.90	Yes
N2 Station 7: SubCarinal Nodes	0.59	0.076	0.92	0.145	0.65	Yes

N2 Station 8: Paraesophageal Nodes	0.66	0.080	0.97	0.070	0.88	Yes
N2 Station 9: Pulmonary Ligament Nodes Left	0.38	0.211	0.94	0.094	0.80	Yes
N2 Station 9: Pulmonary Ligament Nodes Right	0.39	0.156	0.95	0.079	0.84	Yes
Optic Chiasm	0.37	0.178	0.82	0.153	0.61	Yes
Optic Nerve Left	0.63	0.118	0.89	0.123	0.70	Yes
Optic Nerve Right	0.63	0.100	0.91	0.112	0.74	Yes
Oral Cavity	0.89	0.048	0.93	0.188	0.57	Yes
Pancreas	0.68	0.136	0.98	0.059	0.93	Yes
Parotid Gland Left	0.85	0.079	0.95	0.121	0.83	Yes
Parotid Gland Right	0.85	0.070	0.94	0.158	0.82	Yes
Penile Bulb	0.74	0.091	0.94	0.115	0.74	Yes
Pharyngeal Constrictor Muscle Inferior	0.78	0.048	0.96	0.022	0.91	Yes
Pharyngeal Constrictor Muscle Middle	0.67	0.075	0.93	0.086	0.86	Yes
Pharyngeal Constrictor Muscle Superior	0.66	0.055	0.88	0.157	0.53	Yes
Pituitary Gland	0.76	0.074	0.95	0.056	0.86	Yes
Prostate	0.87	0.055	0.97	0.106	0.86	Yes
Proximal Bronchial Tree	0.84	0.050	0.99	0.006	0.98	Yes
Proximal Femur Left	0.93	0.027	0.99	0.015	0.98	Yes
Proximal Femur Right	0.92	0.027	0.99	0.016	0.96	Yes
Pulmonary Artery	0.80	0.057	0.98	0.051	0.97	Yes
Rectum	0.82	0.090	0.97	0.102	0.88	Yes
Rib Left 1	0.84	0.042	0.99	0.009	0.97	Yes
Rib Left 10	0.77	0.184	0.98	0.028	0.96	Yes
Rib Left 11	0.77	0.185	0.98	0.013	0.96	Yes
Rib Left 12	0.80	0.071	0.97	0.031	0.94	Yes
Rib Left 2	0.83	0.073	0.98	0.007	0.97	Yes
Rib Left 3	0.82	0.037	0.98	0.007	0.97	Yes
Rib Left 4	0.83	0.032	0.98	0.050	0.97	Yes
Rib Left 5	0.83	0.031	0.98	0.009	0.97	Yes
Rib Left 6	0.84	0.024	0.98	0.009	0.97	Yes
Rib Left 7	0.83	0.030	0.97	0.081	0.97	Yes
Rib Left 8	0.82	0.035	0.98	0.023	0.97	Yes
Rib Left 9	0.82	0.023	0.98	0.066	0.97	Yes
Rib Right 1	0.84	0.050	0.99	0.012	0.97	Yes
Rib Right 10	0.79	0.189	0.98	0.064	0.96	Yes
Rib Right 11	0.78	0.188	0.98	0.011	0.96	Yes
Rib Right 12	0.82	0.043	0.97	0.044	0.92	Yes
Rib Right 2	0.87	0.026	0.98	0.018	0.97	Yes
Rib Right 3	0.85	0.038	0.98	0.045	0.97	Yes
Rib Right 4	0.86	0.026	0.98	0.080	0.97	Yes
Rib Right 5	0.86	0.025	0.98	0.068	0.97	Yes

Rib Right 6	0.86	0.025	0.98	0.015	0.97	Yes
Rib Right 7	0.85	0.030	0.98	0.015	0.97	Yes
Rib Right 8	0.81	0.106	0.98	0.009	0.97	Yes
Rib Right 9	0.79	0.195	0.98	0.046	0.97	Yes
Sacrum	0.91	0.040	0.98	0.066	0.96	Yes
Seminal Vesicles	0.77	0.097	0.93	0.112	0.76	Yes
Sigmoid	0.80	0.107	0.96	0.099	0.78	Yes
Spinal Canal	0.85	0.071	0.98	0.010	0.97	Yes
Spinal Cord	0.67	0.101	0.98	0.013	0.96	Yes
Spleen	0.93	0.021	1.00	0.008	0.99	Yes
Sternum	0.88	0.031	0.99	0.007	0.98	Yes
Stomach	0.91	0.042	0.99	0.057	0.97	Yes
Submandibular Gland Left	0.87	0.044	0.94	0.104	0.86	Yes
Submandibular Gland Right	0.85	0.064	0.93	0.111	0.79	Yes
Supraglottic Larynx Brouwer et al.	0.77	0.089	0.95	0.036	0.88	Yes
Supraglottic Larynx DAHANCA	0.77	0.089	0.96	0.038	0.91	Yes
Thyroid	0.84	0.034	0.96	0.045	0.88	Yes
Trachea	0.89	0.045	1.00	0.005	0.98	Yes
Uterus	0.88	0.044	0.95	0.113	0.84	Yes
Vena Cava Inferior	0.76	0.126	0.99	0.026	0.97	Yes
Vena Cava Superior	0.79	0.068	0.98	0.028	0.95	Yes
Ventricle Left	0.86	0.041	0.99	0.009	0.98	Yes
Ventricle Left Endocardium	0.84	0.053	0.99	0.006	0.99	Yes
Ventricle Right	0.85	0.017	0.99	0.005	0.99	Yes

Table 10: Robustness assessment of structures for different image contrasts.

Structure	Reference Standard: syngo.via RTiS VC10		Subject Device			Robustness shown
	DICE		DICE			
	Mean	Std. Dev	Mean	Std. Dev	Lower 95th % Confidence Interval	
Abdominopelvic Cavity	0.93	0.032	0.99	0.007	0.98	Yes
Aorta	0.87	0.032	0.97	0.065	0.94	Yes
Atrium Left	0.86	0.048	0.98	0.010	0.97	Yes
Atrium Right	0.79	0.088	0.98	0.010	0.96	Yes
Bladder	0.95	0.050	0.98	0.031	0.95	Yes
Body	0.99	0.003	1.00	0.000	1.00	Yes
Bowel Bag	0.95	0.036	0.99	0.017	0.97	Yes
Bowel Large	0.90	0.046	0.98	0.025	0.95	Yes
Bowel Small	0.89	0.044	0.98	0.031	0.94	Yes
Brachial Plexus Left	0.63	0.086	0.89	0.069	0.77	Yes
Brachial Plexus Right	0.66	0.050	0.89	0.071	0.77	Yes
Brain	0.98	0.005	0.99	0.012	0.97	Yes
Brainstem Brouwer et al.	0.89	0.023	0.94	0.111	0.88	Yes

Brainstem DAHANCA	0.89	0.023	0.94	0.097	0.87	Yes
CA Left Anterior Descending Artery (LAD)	0.48	0.097	0.81	0.083	0.69	Yes
Chest Wall Left	0.92	0.015	0.98	0.014	0.97	Yes
Chest Wall Right	0.93	0.012	0.98	0.012	0.97	Yes
Cochlea Left	0.75	0.161	0.82	0.215	0.32	Yes
Cochlea Right	0.80	0.048	0.83	0.203	0.32	Yes
Duodenum	0.77	0.101	0.95	0.069	0.84	Yes
Esophagus DAHANCA	0.81	0.059	0.94	0.036	0.88	Yes
Esophagus RTOG	0.81	0.059	0.96	0.029	0.91	Yes
Eye Globe Left	0.89	0.037	0.98	0.012	0.96	Yes
Eye Globe Right	0.89	0.026	0.98	0.033	0.92	Yes
Female Breast Left ESTRO	0.89	0.046	0.98	0.063	0.95	Yes
Female Breast Left RTOG	0.89	0.046	0.96	0.040	0.91	Yes
Female Breast Right ESTRO	0.85	0.061	0.99	0.014	0.96	Yes
Female Breast Right RTOG	0.85	0.061	0.96	0.048	0.89	Yes
Femoral Head Left	0.95	0.011	0.98	0.043	0.97	Yes
Femoral Head Right	0.95	0.013	0.99	0.015	0.96	Yes
Glottis Brouwer et al.	0.70	0.100	0.91	0.089	0.77	Yes
Glottis DAHANCA	0.70	0.100	0.93	0.097	0.80	Yes
Heart	0.92	0.027	0.99	0.015	0.97	Yes
Hip Bone Left	0.93	0.016	0.99	0.010	0.97	Yes
Hip Bone Right	0.94	0.013	0.99	0.009	0.97	Yes
Humeral Head Left	0.94	0.021	0.98	0.056	0.97	Yes
Humeral Head Right	0.95	0.032	0.98	0.063	0.96	Yes
Kidney Left	0.93	0.018	0.99	0.033	0.97	Yes
Kidney Right	0.91	0.067	0.99	0.023	0.98	Yes
Lacrimal Gland Left	0.72	0.073	0.96	0.033	0.90	Yes
Lacrimal Gland Right	0.70	0.123	0.94	0.070	0.83	Yes
Lens Left	0.68	0.188	0.93	0.130	0.74	Yes
Lens Right	0.67	0.118	0.95	0.098	0.87	Yes
Lips	0.79	0.070	0.92	0.135	0.86	Yes
Liver	0.96	0.013	0.99	0.008	0.98	Yes
LN Axilla Level I Left	0.81	0.054	0.97	0.017	0.94	Yes
LN Axilla Level I Right	0.80	0.071	0.97	0.018	0.94	Yes
LN Axilla Level II Left	0.79	0.067	0.97	0.025	0.93	Yes
LN Axilla Level II Right	0.78	0.069	0.97	0.019	0.94	Yes
LN Axilla Level III Left	0.75	0.041	0.96	0.028	0.91	Yes
LN Axilla Level III Right	0.76	0.076	0.96	0.025	0.91	Yes
LN Common Iliac Left	0.85	0.052	0.88	0.162	0.53	Yes
LN Common Iliac Right	0.82	0.047	0.88	0.161	0.54	Yes
LN External Iliac Left	0.89	0.035	0.93	0.106	0.83	Yes
LN External Iliac Right	0.88	0.030	0.94	0.060	0.85	Yes
LN Internal Iliac Left	0.83	0.070	0.93	0.092	0.83	Yes
LN Internal Iliac Right	0.84	0.061	0.92	0.083	0.81	Yes
LN Internal Mammary Left	0.59	0.080	0.93	0.061	0.81	Yes
LN Internal Mammary Right	0.63	0.094	0.93	0.078	0.85	Yes

LN Level Ia Submental Triangle	0.64	0.156	0.88	0.140	0.60	Yes
LN Level Ib Submandibular Triangle Left	0.80	0.062	0.92	0.136	0.76	Yes
LN Level Ib Submandibular Triangle Right	0.77	0.085	0.91	0.131	0.62	Yes
LN Level II Upper Jugular Nodes Left	0.82	0.051	0.93	0.099	0.83	Yes
LN Level II Upper Jugular Nodes Right	0.80	0.062	0.92	0.089	0.71	Yes
LN Level III Middle Jugular Nodes Left	0.79	0.067	0.92	0.070	0.79	Yes
LN Level III Middle Jugular Nodes Right	0.77	0.085	0.85	0.214	0.28	Yes
LN Level IVa Lower Jugular Group Left	0.71	0.108	0.87	0.167	0.55	Yes
LN Level IVa Lower Jugular Group Right	0.73	0.084	0.82	0.226	0.30	Yes
LN Level IVb Medial Supraclavicular Group Left	0.66	0.157	0.89	0.125	0.62	Yes
LN Level IVb Medial Supraclavicular Group Right	0.70	0.109	0.90	0.093	0.72	Yes
LN Level IX Bucco-facial Group Left	0.63	0.115	0.92	0.091	0.83	Yes
LN Level IX Bucco-facial Group Right	0.60	0.123	0.92	0.068	0.84	Yes
LN Level V Posterior Triangle Group Left	0.71	0.116	0.91	0.117	0.71	Yes
LN Level V Posterior Triangle Group Right	0.69	0.121	0.90	0.124	0.71	Yes
LN Level Vc Lateral Supraclavicular Group Left	0.56	0.154	0.90	0.108	0.77	Yes
LN Level Vc Lateral Supraclavicular Group Right	0.61	0.122	0.88	0.112	0.69	Yes
LN Level VIa Anterior Jugular Nodes	0.70	0.066	0.86	0.175	0.58	Yes
LN Level VIb Prelaryngeal, Pretracheal, & Paratracheal Nodes	0.66	0.108	0.86	0.192	0.45	Yes
LN Level VIIa Retropharyngeal Nodes Left	0.53	0.100	0.86	0.148	0.61	Yes
LN Level VIIa Retropharyngeal Nodes Right	0.49	0.148	0.84	0.162	0.60	Yes
LN Level VIIb Retro-styloid Nodes Left	0.73	0.079	0.90	0.141	0.67	Yes
LN Level VIIb Retro-styloid Nodes Right	0.74	0.094	0.89	0.146	0.55	Yes

LN Level VIII Parotid Group Left	0.85	0.037	0.93	0.133	0.80	Yes
LN Level VIII Parotid Group Right	0.84	0.042	0.93	0.091	0.81	Yes
LN Level Xa Retroauricular & Subauricular Nodes Left	0.69	0.099	0.93	0.095	0.86	Yes
LN Level Xa Retroauricular & Subauricular Nodes Right	0.73	0.074	0.94	0.048	0.86	Yes
LN Level Xb Occipital Nodes Left	0.57	0.110	0.91	0.119	0.74	Yes
LN Level Xb Occipital Nodes Right	0.56	0.134	0.89	0.140	0.70	Yes
LN Obturator Left	0.83	0.026	0.95	0.063	0.88	Yes
LN Obturator Right	0.83	0.040	0.94	0.069	0.86	Yes
LN Presacral	0.68	0.140	0.90	0.079	0.77	Yes
LN Supraclavicular Left	0.79	0.083	0.96	0.027	0.92	Yes
LN Supraclavicular Right	0.80	0.067	0.96	0.032	0.91	Yes
Lung Lobe Left Lower	0.90	0.121	0.99	0.029	0.98	Yes
Lung Lobe Left Upper	0.94	0.071	1.00	0.006	0.99	Yes
Lung Lobe Right Lower	0.93	0.044	0.99	0.065	0.99	Yes
Lung Lobe Right Middle	0.89	0.077	0.98	0.091	0.93	Yes
Lung Lobe Right Upper	0.93	0.052	0.99	0.015	0.98	Yes
Mandible	0.88	0.027	0.95	0.068	0.89	Yes
N1 Station 10: Hilar Nodes Left	0.53	0.097	0.88	0.163	0.57	Yes
N1 Station 10: Hilar Nodes Right	0.50	0.095	0.91	0.108	0.79	Yes
N2 Station 1: Highest Mediastinal Nodes Left	0.71	0.100	0.91	0.107	0.73	Yes
N2 Station 1: Highest Mediastinal Nodes Right	0.66	0.128	0.90	0.126	0.70	Yes
N2 Station 2: Upper Paratracheal Nodes Left	0.68	0.076	0.89	0.169	0.60	Yes
N2 Station 2: Upper Paratracheal Nodes Right	0.56	0.136	0.90	0.119	0.69	Yes
N2 Station 3A: Prevascular Nodes	0.76	0.063	0.88	0.223	0.23	Yes
N2 Station 3P: Retrotracheal Nodes	0.66	0.060	0.82	0.264	0.04	Yes
N2 Station 4: Lower Paratracheal Nodes Left	0.66	0.084	0.91	0.118	0.79	Yes
N2 Station 4: Lower Paratracheal Nodes Right	0.73	0.080	0.92	0.131	0.82	Yes
N2 Station 5: Subaortic Nodes	0.61	0.148	0.90	0.134	0.79	Yes
N2 Station 6: Para-aortic Nodes	0.59	0.148	0.90	0.102	0.78	Yes

N2 Station 7: SubCarinal Nodes	0.59	0.076	0.81	0.251	0.06	Yes
N2 Station 8: Paraesophageal Nodes	0.66	0.080	0.88	0.156	0.56	Yes
N2 Station 9: Pulmonary Ligament Nodes Left	0.38	0.211	0.81	0.147	0.52	Yes
N2 Station 9: Pulmonary Ligament Nodes Right	0.39	0.156	0.82	0.146	0.57	Yes
Optic Chiasm	0.37	0.178	0.68	0.251	0.09	Yes
Optic Nerve Left	0.63	0.118	0.89	0.132	0.67	Yes
Optic Nerve Right	0.63	0.100	0.86	0.181	0.45	Yes
Oral Cavity	0.89	0.048	0.93	0.189	0.81	Yes
Pancreas	0.68	0.136	0.92	0.109	0.78	Yes
Parotid Gland Left	0.85	0.079	0.93	0.128	0.83	Yes
Parotid Gland Right	0.85	0.070	0.93	0.142	0.76	Yes
Penile Bulb	0.74	0.091	0.90	0.159	0.60	Yes
Pharyngeal Constrictor Muscle Inferior	0.78	0.048	0.92	0.064	0.81	Yes
Pharyngeal Constrictor Muscle Middle	0.67	0.075	0.92	0.092	0.80	Yes
Pharyngeal Constrictor Muscle Superior	0.66	0.055	0.89	0.120	0.66	Yes
Pituitary Gland	0.76	0.074	0.91	0.148	0.75	Yes
Prostate	0.87	0.055	0.91	0.190	0.46	Yes
Proximal Bronchial Tree	0.84	0.050	0.99	0.009	0.97	Yes
Proximal Femur Left	0.93	0.027	0.98	0.057	0.94	Yes
Proximal Femur Right	0.92	0.027	0.98	0.038	0.94	Yes
Pulmonary Artery	0.80	0.057	0.96	0.060	0.93	Yes
Rectum	0.82	0.090	0.95	0.137	0.85	Yes
Rib Left 1	0.84	0.042	0.96	0.020	0.92	Yes
Rib Left 10	0.77	0.184	0.95	0.094	0.90	Yes
Rib Left 11	0.77	0.185	0.95	0.115	0.89	Yes
Rib Left 12	0.80	0.071	0.93	0.127	0.82	Yes
Rib Left 2	0.83	0.073	0.97	0.037	0.94	Yes
Rib Left 3	0.82	0.037	0.97	0.020	0.94	Yes
Rib Left 4	0.83	0.032	0.96	0.091	0.94	Yes
Rib Left 5	0.83	0.031	0.96	0.081	0.94	Yes
Rib Left 6	0.84	0.024	0.97	0.080	0.95	Yes
Rib Left 7	0.83	0.030	0.96	0.108	0.91	Yes
Rib Left 8	0.82	0.035	0.95	0.143	0.91	Yes
Rib Left 9	0.82	0.023	0.96	0.121	0.92	Yes
Rib Right 1	0.84	0.050	0.96	0.022	0.92	Yes
Rib Right 10	0.79	0.189	0.96	0.095	0.92	Yes
Rib Right 11	0.78	0.188	0.96	0.094	0.92	Yes
Rib Right 12	0.82	0.043	0.93	0.124	0.75	Yes
Rib Right 2	0.87	0.026	0.96	0.075	0.93	Yes
Rib Right 3	0.85	0.038	0.96	0.086	0.93	Yes

Rib Right 4	0.86	0.026	0.96	0.117	0.93	Yes
Rib Right 5	0.86	0.025	0.96	0.092	0.93	Yes
Rib Right 6	0.86	0.025	0.96	0.080	0.94	Yes
Rib Right 7	0.85	0.030	0.96	0.078	0.93	Yes
Rib Right 8	0.81	0.106	0.96	0.075	0.93	Yes
Rib Right 9	0.79	0.195	0.96	0.089	0.93	Yes
Sacrum	0.91	0.040	0.96	0.112	0.92	Yes
Seminal Vesicles	0.77	0.097	0.86	0.204	0.39	Yes
Sigmoid	0.80	0.107	0.92	0.156	0.59	Yes
Spinal Canal	0.85	0.071	0.97	0.016	0.95	Yes
Spinal Cord	0.67	0.101	0.95	0.026	0.90	Yes
Spleen	0.93	0.021	0.99	0.010	0.98	Yes
Sternum	0.88	0.031	0.96	0.042	0.90	Yes
Stomach	0.91	0.042	0.97	0.073	0.89	Yes
Submandibular Gland Left	0.87	0.044	0.92	0.142	0.80	Yes
Submandibular Gland Right	0.85	0.064	0.91	0.148	0.67	Yes
Supraglottic Larynx Brouwer et al.	0.77	0.089	0.95	0.044	0.86	Yes
Supraglottic Larynx DAHANCA	0.77	0.089	0.93	0.092	0.83	Yes
Thyroid	0.84	0.034	0.91	0.083	0.77	Yes
Trachea	0.89	0.045	0.99	0.007	0.98	Yes
Uterus	0.88	0.044	0.88	0.188	0.54	Yes
Vena Cava Inferior	0.76	0.126	0.96	0.059	0.93	Yes
Vena Cava Superior	0.79	0.068	0.96	0.052	0.90	Yes
Ventricle Left	0.86	0.041	0.95	0.041	0.92	Yes
Ventricle Left Endocardium	0.84	0.053	0.97	0.015	0.95	Yes
Ventricle Right	0.85	0.017	0.98	0.012	0.96	Yes

MR Autocontouring

The algorithms were evaluated on 294 (252 unique) subjects. The test data collection is subdivided into three cohorts i.e., cohort A for Brain Metastases algorithm, cohort B for Brain OAR algorithm and cohort C for Pelvis OAR algorithms (T1 and T2 models) testing. The MR Brain Metastases algorithm was tested on 60 subjects The MR Brain OAR algorithm was tested on 81 subjects. The MR Pelvis OAR algorithms were tested on 153 subjects.

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.

Table 11: Quantitative evaluation results of Lesionwise DICE for brain metastases in the subject device.

Structure	Reference DICE Mean	Subject DICE Mean	Subject DICE Std	Lower 95th Confidence Interval	Equivalence Shown
Brain metastases	0.79	0.74	0.17	0.72	Yes

Table 12: Quantitative evaluation results of Lesionwise Sensitivity for brain metastases in the subject device.

Structure	Reference Sensitivity Mean (%)	Subject Sensitivity Mean (%)	Subject Sensitivity Std (%)	Lower 95th Confidence Interval	Equivalence Shown
Brain metastases	90.3	92.5	3.4	85.80	Yes

Brain and Pelvis OAR

The 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. Average user evaluation of 3 or higher (3: usable with minor edits, 4: clinically usable).

Table 13: Quantitative evaluation results of DICE for Brain OAR structures in the subject device.

Organ	*Reference Standard*: syngo.via RTiS VC10	*Subject Device*			*Equivalence shown*
	Dice Mean	*Dice Mean*	*Dice Std*	*Lower 95th Confidence Interval*	
Brain OAR					
Brainstem	0.90	0.93	0.02	0.92	Yes
Cochlea Left	0.5	0.50	0.18	0.46	Yes
Cochlea Right	0.5	0.49	0.19	0.45	Yes
Cornea Left	0.5	0.52	0.16	0.48	Yes
Cornea Right	0.5	0.53	0.15	0.50	Yes
Eye Left	0.89±0.04	0.92	0.05	0.90	Yes
Eye Right	0.89±0.03	0.92	0.03	0.92	Yes
Hippocampus Left	0.66	0.77	0.07	0.75	Yes
Hippocampus Right	0.71	0.76	0.08	0.75	Yes
Lacrimal Gland Left	0.46	0.56	0.20	0.51	Yes
Lacrimal Gland Right	0.55	0.57	0.20	0.52	Yes
Lens Left	0.68±0.19	0.75	0.14	0.71	Yes
Lens Right	0.66±0.12	0.77	0.15	0.73	Yes
Optic Chiasm	0.55	0.66	0.11	0.63	Yes
Optic Nerve Left	0.49	0.54	0.15	0.51	Yes
Optic Nerve Right	0.56	0.57	0.14	0.54	Yes
Pituitary Gland	0.61	0.65	0.17	0.61	Yes
Retina Left	0.5	0.62	0.15	0.59	Yes
Retina Right	0.5	0.63	0.11	0.60	Yes

Spinal cord	0.68±0.10	0.86	0.09	0.84	Yes
T1 Pelvis OAR					
Body	0.98	0.98	0.01	0.98	Yes
Femur head Left	0.94	0.93	0.03	0.92	Yes
Femur head Right	0.94	0.94	0.02	0.93	Yes
T2 Pelvis OAR					
Anus	0.76	0.73	0.10	0.71	Yes
Bladder	0.91	0.90	0.08	0.88	Yes
Penile Bulb	0.82	0.81	0.09	0.79	Yes
Prostate	0.85	0.86	0.07	0.84	Yes
Rectum	0.85	0.86	0.06	0.85	Yes
Seminal Vesicles	0.66	0.72	0.14	0.69	Yes

Table 14: Quantitative evaluation results of ASSD for Brain OAR structures in the subject device.

Structure	***Reference Standard***	***Subject Device***			***Equivalence shown***
	MD/ASSD Mean±Std	***ASSD Mean (mm)***	***ASSD Std (mm)***	***Upper 95% Confidence Interval (mm)***	
Brain OAR					
Brainstem	0.9±0.16	0.54	0.15	0.57	Yes
Cochlea Left	NA	1.11	0.84	1.30	-
Cochlea Right	NA	1.07	0.76	1.23	-
Cornea Left	0.60±0.21	0.59	0.35	0.66	Yes
Cornea Right	0.60±0.21	0.66	0.80	0.83	No
Eye Left	0.60±0.24	0.40	0.24	0.45	Yes
Eye Right	0.62±0.17	0.36	0.15	0.40	Yes
Hippocampus Left	0.75±0.75	0.72	0.36	0.79	Yes
Hippocampus Right	0.67±0.47	0.71	0.31	0.77	Yes
Lacrimal Gland Left	1.39±0.97	1.60	1.58	1.95	Yes
Lacrimal Gland Right	1.31±0.95	1.48	1.30	1.77	Yes
Lens Left	0.61±0.56	0.43	0.30	0.50	Yes
Lens Right	0.60±0.25	0.42	0.36	0.50	Yes
Optic Chiasm	0.69±0.80	0.69	0.66	0.84	Yes
Optic Nerve Left	1.47±2.17	1.21	2.70	1.80	Yes
Optic Nerve Right	0.95±0.65	0.85	0.86	1.04	Yes

Pituitary Gland	0.94±0.26	0.76	0.47	0.86	Yes
Retina Left	0.61±0.21	0.43	0.50	0.54	Yes
Retina Right	0.61±0.21	0.38	0.14	0.40	Yes
Spinal cord	1.70±0.72	0.51	0.47	0.61	Yes
T1 Pelvis OAR					
Body	2.07±1.81	1.40	1.56	1.82	Yes
Femur head Left	0.85±0.59	1.10	0.59	1.26	Yes
Femur head Right	0.88±0.54	0.96	0.48	1.09	Yes
T2 Pelvis OAR					
Anus	2.09±0.9	2.24	1.16	2.47	Yes
Bladder	1.44±0.89	1.36	0.85	1.53	Yes
Penile Bulb	0.79±0.75	0.91	0.76	1.07	Yes
Prostate	1.56±0.54	1.66	2.01	2.08	Yes
Rectum	2.34±2.17	1.92	2.01	2.32	Yes
Seminal Vesicles	2.43±2.61	1.78	1.25	2.05	Yes

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.

ISO 14971:2022	Medical devices - Application of risk management to medical devices
ISO 15223-1:2022	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2022	Information supplied by the manufacturer of medical devices
IEC 62304:2006 + A1:2016	Medical Device Software - Software Lifecycle processes
IEC 62366-1:2021	Application of Usability Engineering to Medical Devices
IEC 82304-1:2018	Health software Part 1: General requirements for product safety

Risk Management

Risk management is conducted in compliance with EN ISO 14971:2019 and Siemens Healthineers' internal process (QR7). Hazards and risks are systematically identified, evaluated, and mitigated through defined control measures. These are verified, validated, and continuously monitored through post-market surveillance (PMS) and post-market clinical follow-up (PMCF).

The latest risk documentation reflects adjustments to risk evaluations, removal of obsolete hazards, and validation of updated control measures. Usability-related risks and software warnings have been reviewed, with relevant IFU content and GUI messages updated accordingly.

IX. Determination of Substantial Equivalence to the Predicate

AI Contouring contains a subset of software features and characteristics of the predicate and references devices. 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 and effective as the predicate. AI Contouring VA10A is comparable to AI-Rad Companion Organs RT and has similar performance metrics. Varian therefore believes that the subject device is substantially equivalent to the predicate device.