Radformation, Inc.
% Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 4th floor
New York, New York 10017

Re: K220598
Trade/Device Name: AutoContour Model RADAC V2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: July 22, 2022
Received: July 27, 2022

Dear Kurt Sysock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Julie Sullivan, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220598

Device Name
AutoContour RADAC V2

Indications for Use *(Describe)*

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

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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This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1. Submitter's Information

Table 1 : Submitter's Information	
Submitter's Name:	Kurt Sysock
Company:	Radformation, Inc.
Address:	335 Madison Avenue, 4th Floor New York, NY 10017
Contact Person:	Alan Nelson Chief Science Officer, Radformation
Phone:	518-888-5727
Fax:	---------
Email:	anelson@radformation.com
Date of Summary Preparation	08/22/2022

5.2. Device Information

Table 2 : Device Information	
Trade Name:	AutoContour RADAC V2
Common Name:	Radiological Image Processing Software For Radiation Therapy
Classification Name:	Class II
Classification:	Medical image management and processing system
Regulation Number:	892.2050
Product Code:	QKB
Classification Panel:	Radiology

5.3. Predicate Device Information

AutoContour RADAC V2 (Subject Device) makes use of its prior submission - AutoContour RADAC (K200323) - as the Predicate Device.
Contour ProtégéAI (K213976) - as a Reference Device.

5.4. Device Description

As with AutoContour RADAC, the AutoContour RADAC V2 device is software that uses DICOM-compliant image data (CT or MR) as input to (1) automatically contour various structures of interest for radiation therapy treatment planning using machine learning based contouring. The deep-learning based structure models are trained using imaging datasets consisting of anatomical organs of the head and neck, thorax, abdomen and pelvis for adult male and female patients.(2) allow the user to review and modify the resulting contours, and (3) generate DICOM-compliant structure set data the can be imported into a radiation therapy treatment planning system

AutoContour RADAC V2 consists of 3 main components:

1. A .NET client application designed to run on the Windows Operating System allowing the user to load image and structure sets for upload to the cloud-based server for automatic contouring, perform registration with other image sets, as well as review, edit, and export the structure set.
2. A local “agent” service designed to run on the Windows Operating System that is configured by the user to monitor a network storage location for new CT and MR datasets that are to be automatically contoured.
3. A cloud-based automatic contouring service that produces initial contours based on image sets sent by the user from the .NET client application.

5.5. Indications for Use

AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.

5.6. Technological Characteristics

Subject Device, AutoContour RADAC V2 makes use of a Predicate Device, AutoContour RADAC (K200323) as the Predicate Device for substantial equivalence comparison. The functionality and technical components of this prior submission remain unchanged in AutoContour RADAC V2. This submission is intended to build on the functionality and technological components of the 510(k) cleared AutoContour RADAC.

5.6.1. Updates vs. AutoContour (K200323)

The updated submissions expanded the machine-learning based contouring and manual ROI manipulation to Magnetic Resonance (MR) image types as well as expanded the number of supported CT structure models. Additionally, image registration is expanded to include deformable image registration for the purposes of transferring structure contours from one image set to another.

Table 3: Technological Characteristics AutoContour RADAC V2 vs. AutoContour RADAC (K200323)		
Characteristic	Subject Device: AutoContour RADAC V2	Predicate Device: AutoContour RADAC (K200323)
Design: Image registration	Manual **and Automatic** Rigid registration. **Automatic Deformable Registration**	Manual Rigid registration.
Design: Supported modalities	CT **or MR** input for contouring or registration/fusion. **PET/CT** input for registration/fusion only. DICOM RTSTRUCT for output	CT input for contouring or manual registration/fusion. MR, **PET/CT** input for manual registration/fusion only. DICOM RTSTRUCT for output
Regions and Volumes of interest (ROI)	CT **or MR** input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis. CT Models: ● ***A_Aorta*** ● ***A_Aorta_Asc*** ● ***A_Aorta_Dsc*** ● ***A_LAD*** ● Bladder ● ***Bone_Ilium_L*** ● ***Bone_Ilium_R*** ● Bone_Mandible ● ***Bowel_Bag*** ● ***BrachialPlex_L*** ● ***BrachialPlex_R*** ● Brain ● Brainstem ● ***Breast_L*** ● ***Breast_R*** ● Bronchus ● Carina ● ***CaudaEquina*** ● Cavity_Oral ● Cochlea_L ● Cochlea_R ● ***Ear_Internal_L*** ● ***Ear_Internal_R*** ● Esophagus ● ***External*** ● Eye_L ● Eye_R ● Femur_L ● Femur_R ● ***Femur_RTOG_L***	CT input for contouring of anatomical regions: Head and Neck, Thorax, Abdomen and Pelvis. CT Models: ● Bladder ● Bone_Mandible ● Brain ● Brainstem ● Bronchus ● Bronchus_Main ● Carina ● Cavity_Oral ● Cochlea_L ● Cochlea_R ● Esophagus ● Eye_L ● Eye_R ● Femur_L ● Femur_R ● Glnd_Lacrimal_L ● Glnd_Lacrimal_R ● Glnd_Submand_L ● Glnd_Submand_R ● Heart ● Kidney_L ● Kidney_R ● Lens_L ● Lens_R ● Liver ● Lung_L ● Lung_R ● OpticNrv_L ● OpticNrv_R ● Parotid_L

	• ***Femur_RTOG_R*** • Glnd_Lacrimal_L • Glnd_Lacrimal_R • Glnd_Submand_L • Glnd_Submand_R • ***Glnd_Thyroid*** • ***HDR_Cylinder*** • Heart • ***Humerus_L*** • ***Humerus_R*** • Kidney_L • Kidney_R • ***Kidney_Outer_L*** • ***Kidney_Outer_R*** • ***Larynx*** • Lens_L • Lens_R • ***Lips*** • ***LN_Ax_L*** • ***LN_Ax_R*** • ***LN_IMN_L*** • ***LN_IMN_R*** • ***LN_Neck_IA*** • ***LN_Neck_IB-V_L*** • ***LN_Neck_IB-V_R*** • ***LN_Neck_II_L*** • ***LN_Neck_II_R*** • ***LN_Neck_II-IV_L*** • ***LN_Neck_II-IV_R*** • ***LN_Neck_III_L*** • ***LN_Neck_III_R*** • ***LN_Neck_IV_L*** • ***LN_Neck_IV_R*** • ***LN_Neck_VIA*** • ***LN_Neck_VIIA_L*** • ***LN_Neck_VIIA_R*** • ***LN_Neck_VIIB_L*** • ***LN_Neck_VIIB_R*** • ***LN_Pelvics*** • ***LN_Sclav_L*** • ***LN_Sclav_R*** • Liver • Lung_L • Lung_R • ***Marrow_Ilium_L*** • ***Marrow_Ilium_R*** • ***Musc_Constrict*** • OpticChiasm • OpticNrv_L • OpticNrv_R • Parotid_L • Parotid_R • ***PenileBulb*** • ***Pituitary*** • Prostate • Rectum • ***Rib*** • ***SeminalVes*** • ***SpinalCanal*** • SpinalCord • Stomach	• Parotid_R • Prostate • Rectum • SpinalCord • Stomach

	● ***Trachea*** ● ***V_Venacava_S*** MR Models: ● ***OpticChiasm*** ● ***OpticNrv_L*** ● ***OpticNrv_R*** ● ***Brainstem*** ● ***Hippocampus_L*** ● ***Hippocampus_R***	
Computer platform & operating system	Windows based .NET front-end application that also serves as agent Uploader supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016. Cloud-based Server based automatic contouring application compatible with Linux. Windows python-based automatic contouring application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016.	Agent Uploader supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016. Cloud-based Server based automatic contouring application compatible with Linux. Web application Server based application compatible with Linux with frontend compatible with all modern web browsers.

As shown in Table 3, almost all technological characteristics are either substantially equivalent or a subset of the Predicate Device' technological characteristics.

5.7. Discussion of differences

Subset of the Predicate Device

The comparison table above shows that several features of AutoContour RADAC V2 are minor expansions of features that were previously submitted, and therefore these differences do not create new questions regarding the safety and effectiveness of the device relative to the previous submission.

Minor differences

The following minor differences exist, but do not represent any significant additional risks or decreased effectiveness for the device for its intended use:

- **Design: Supported modalities:** AutoContour RADAC V2 now supports MR Image types along with CT for automatic contouring. Similar contour validation was performed on MR models as was performed previously with CT-based contour models and therefore do not represent any significant additional risks or decreased effectiveness for the device for its

intended use. The following MR models are supported in AutoContour RADAC V2:

- ***OpticChiasm***
- ***OpticNrv_L***
- ***OpticNrv_R***
- ***Brainstem***
- ***Hippocampus_L***
- ***Hippocampus_R***

- **Design: Image Registration:** AutoContour RADAC V2 supports automatic deformable image registration along with rigid registration. Similar registration validation was performed on automatic deformable image registration as was performed previously and therefore does not represent any significant additional risks or decreased effectiveness for the device for its intended use.
- **Compatibility with the environment and other devices / Computer platform & operating system: Local Automatic Contouring Processor**: AutoContour RADAC V2 allows for automatic contouring to be generated locally. Automatic Contour algorithms and models are identical to that available on the Cloud-Based servers and therefore do not represent any significant additional risks or decreased effectiveness for the device for its intended use.
- **Compatibility with the environment and other devices / Computer platform & operating system: Local Automatic Contouring Processor**: The AutoContour RADAC V2 front-end interface and agent uploader is built using a .NET Framework application compatible with Windows devices. The updated front-end platform and uploader agent do not represent any significant additional risks or decreased effectiveness for the device for its intended use.
- **New CT Models:**
  Compared with the predicate device, AutoContour RADAC V2 supports contouring 58 new models on CT images (the new models are listed below).

  The addition of these models do not represent a significant deviation from the intended use and operation of AutoContour, nor does it represent a new significant unmitigated risk because:
  (a) the same CNN architecture was used to train these new CT models
  (b) all new models passed the same DSC test protocol criteria for similar structure sizes. All models were also tested with sensitivity and specificity analysis, inter-observer variability testing, and expert user evaluation like the predicate device and the results of these tests support substantial equivalence in the effectiveness of the new models compared with the predicate device models.
  (c) the same risk mitigations that have been applied to the predicate device models have also been applied to all new models including

appropriate labeling mitigations and a process for required review and approval of structures in the application prior to being able to export them.

- ***A_Aorta***
- ***A_Aorta_Asc***
- ***A_Aorta_Dsc***
- ***A_LAD***
- ***Bone_Ilium_L***
- ***Bone_Ilium_R***
- ***Bowel_Bag***
- ***BrachialPlex_L***
- ***BrachialPlex_R***
- ***Breast_L***
- ***Breast_R***
- ***CaudaEquina***
- ***Ear_Internal_L***
- ***Ear_Internal_R***
- ***External***
- ***Femur_RTOG_L***
- ***Femur_RTOG_R***
- ***Glnd_Thyroid***
- ***HDR_Cylinder***
- ***Humerus_L***
- ***Humerus_R***
- ***Kidney_Outer_L***
- ***Kidney_Outer_R***
- ***Larynx***
- ***Lips***
- ***LN_Ax_L***
- ***LN_Ax_R***
- ***LN_IMN_L***
- ***LN_IMN_R***
- ***LN_Neck_IA***
- ***LN_Neck_IB-V_L***
- ***LN_Neck_IB-V_R***
- ***LN_Neck_II_L***
- ***LN_Neck_II_R***
- ***LN_Neck_II-IV_L***
- ***LN_Neck_II-IV_R***
- ***LN_Neck_III_L***
- ***LN_Neck_III_R***
- ***LN_Neck_IV_L***
- ***LN_Neck_IV_R***
- ***LN_Neck_VIA***
- ***LN_Neck_VIIA_L***

- ***LN_Neck_VIIA_R***
- ***LN_Neck_VIIB_L***
- ***LN_Neck_VIIB_R***
- ***LN_Pelvics***
- ***LN_Sclav_L***
- ***LN_Sclav_R***
- ***Marrow_Ilium_L***
- ***Marrow_Ilium_R***
- ***Musc_Constrict***
- ***PenileBulb***
- ***Pituitary***
- ***Rib***
- ***SeminalVes***
- ***SpinalCanal***
- ***Trachea***
- ***V_Venacava_S***

5.8. Performance Data

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

Sterilization & Shelf-life Testing

AutoContour is a pure software device and is not supplied sterile because the device doesn't come in contact with the patient. AutoContour is a pure software device and does not have a Shelf Life.

Biocompatibility

AutoContour is a pure software device and does not come in contact with the patient.

Electrical safety and electromagnetic compatibility (EMC)

AutoContour is a pure software device hence, no Electromagnetic Compatibility and Electrical Safety testing was conducted for the Subject Device.

Software Verification and Validation Testing

As with the Predicate Device, no clinical trials were performed for AutoContour RADAC V2. Non-clinical tests were performed to demonstrate that AutoContour RADAC V2 performs as intended per its indications for use. Further tests were performed on independent datasets from those included in training and validation sets in order to validate the generalizability of the machine learning model.

Mean Dice Similarity Coefficient (DSC) was used to validate the accuracy of structure model outputs within three size categories. As DSC is sensitive to structure volume, the validation passing criteria was set at a mean DSC exceeding 0.80 for Large volume structures (eg. Liver, Lung), 0.65 for Medium volume structures (eg. Parotid, Eye), and 0.5 for Small structures (eg OpticChiasm, Lens). For CT Large, Medium, and Small structures, AutoContour's results had a mean DSC of 0.94+/-0.03, 0.82+/-0.09, and 0.61+/-0.14 respectively:

Structure	# Training Data Sets	# Test Data Sets	Size	DSC Mean	DSC STD	Lower Bound 95% Confidence Interval
A_Aorta	240	60	Large	0.91	0.03	0.86
A_Aorta_Asc	240	60	Large	0.90	0.03	0.85
A_Aorta_Dsc	240	60	Large	0.93	0.02	0.90
A_LAD	461	116	Small	0.57	0.13	0.36
Bladder	1000	372	Large	0.92	0.09	0.77
Bone_Ilium_L	120	31	Large	0.94	0.01	0.92
Bone_Ilium_R	120	31	Large	0.94	0.01	0.92
Bone_Mandible	230	58	Medium	0.90	0.03	0.85
Bowel_Bag	131	33	Large	0.93	0.04	0.86
BrachialPlex_L	78	20	Medium	0.73	0.08	0.60
BrachialPlex_R	78	20	Medium	0.73	0.08	0.60
Brain	1000	28	Large	0.96	0.01	0.94
Brainstem	236	60	Medium	0.90	0.02	0.87
Breast_L	462	116	Large	0.93	0.04	0.86
Breast_R	462	116	Large	0.93	0.04	0.86
Bronchus	200	50	Medium	0.73	0.09	0.58
Carina	2312	578	Medium	0.82	0.08	0.69
CaudaEquina	87	22	Medium	0.90	0.02	0.87
Cavity_Oral	532	133	Medium	0.83	0.1	0.67
Cochlea_L	106	26	Small	0.65	0.1	0.49
Cochlea_R	106	26	Small	0.65	0.1	0.49
Ear_Internal_L	1289	324	Small	0.64	0.21	0.29
Ear_Internal_R	1289	324	Small	0.64	0.21	0.29
Esophagus	1116	279	Medium	0.76	0.13	0.55

Structure	# Training Data Sets	# Test Data Sets	Size	DSC Mean	DSC STD	Lower Bound 95% Confidence Interval
External	3173	826	Large	0.99	0.04	0.92
Eye_L	336	85	Medium	0.92	0.02	0.89
Eye_R	336	85	Medium	0.92	0.02	0.89
Femur_L	1315	330	Large	0.96	0.06	0.86
Femur_R	1315	330	Large	0.96	0.06	0.86
Femur_RTOG_L	1315	330	Large	0.96	0.06	0.86
Femur_RTOG_R	1315	330	Large	0.96	0.06	0.86
Glnd_Lacrimal_L	353	86	Small	0.54	0.18	0.24
Glnd_Lacrimal_R	353	86	Small	0.54	0.18	0.24
Glnd_Submand_L	814	43	Medium	0.82	0.15	0.57
Glnd_Submand_R	814	43	Medium	0.82	0.15	0.57
Glnd_Thyroid	169	43	Medium	0.79	0.06	0.69
HDR_Cylinder	15	4	Large	0.97	0.01	0.97
Heart	2060	515	Large	0.93	0.05	0.85
Humerus_L	451	114	Large	0.95	0.02	0.92
Humerus_R	451	114	Large	0.95	0.02	0.92
Kidney_L	1083	271	Medium	0.94	0.03	0.89
Kidney_R	1083	271	Medium	0.94	0.03	0.89
Kidney_Outer_L	590	148	Medium	0.93	0.05	0.85
Kidney_Outer_R	590	148	Medium	0.93	0.05	0.85
Larynx	172	43	Medium	0.85	0.05	0.77
Lens_L	1114	278	Small	0.66	0.14	0.43
Lens_R	1114	278	Small	0.66	0.14	0.43
Lips	432	110	Small	0.52	0.16	0.26
LN_Ax_L	437	110	Medium	0.83	0.07	0.71
LN_Ax_R	437	110	Medium	0.83	0.07	0.71
LN_IMN_L	390	97	Medium	0.68	0.07	0.56
LN_IMN_R	390	97	Medium	0.68	0.07	0.56
LN_Neck_IA	272	68	Medium	0.78	0.06	0.68
LN_Neck_IB-V_L	316	79	Medium	0.86	0.05	0.78
LN_Neck_IB-V_R	316	79	Medium	0.86	0.05	0.78

Structure	# Training Data Sets	# Test Data Sets	Size	DSC Mean	DSC STD	Lower Bound 95% Confidence Interval
LN_Neck_II_L	271	68	Medium	0.84	0.04	0.77
LN_Neck_II_R	271	68	Medium	0.84	0.04	0.77
LN_Neck_II-IV_L	325	82	Medium	0.86	0.03	0.81
LN_Neck_II-IV_R	325	82	Medium	0.86	0.03	0.81
LN_Neck_III_L	328	83	Medium	0.80	0.09	0.65
LN_Neck_III_R	328	83	Medium	0.80	0.09	0.65
LN_Neck_IV_L	328	82	Medium	0.77	0.07	0.65
LN_Neck_IV_R	328	82	Medium	0.77	0.07	0.65
LN_Neck_VIA	262	66	Medium	0.79	0.07	0.67
LN_Neck_VIIA_L	272	69	Medium	0.71	0.07	0.59
LN_Neck_VIIA_R	272	69	Medium	0.71	0.07	0.59
LN_Neck_VIIB_L	332	84	Medium	0.79	0.06	0.69
LN_Neck_VIIB_R	332	84	Medium	0.79	0.06	0.69
LN_Pelvics	502	126	Medium	0.87	0.05	0.79
LN_Sclav_L	460	115	Medium	0.88	0.05	0.8
LN_Sclav_R	460	115	Medium	0.88	0.05	0.8
Liver	480	120	Large	0.96	0.02	0.93
Lung_L	3491	748	Large	0.97	0.02	0.94
Lung_R	3491	748	Large	0.97	0.02	0.94
Marrow_Ilium_L	121	31	Large	0.91	0.02	0.88
Marrow_Ilium_R	121	31	Large	0.91	0.02	0.88
Musc_Constrict	272	69	Medium	0.75	0.06	0.65
OpticChiasm	158	40	Small	0.63	0.07	0.51
OpticNrv_L	741	185	Small	0.51	0.18	0.21
OpticNrv_R	741	185	Small	0.51	0.18	0.21
Parotid_L	739	48	Medium	0.82	0.04	0.75
Parotid_R	739	48	Medium	0.82	0.04	0.75
PenileBulb	232	58	Small	0.76	0.09	0.61
Pituitary	201	41	Small	0.68	0.09	0.53
Prostate	708	177	Medium	0.86	0.04	0.79
Rectum	1436	359	Medium	0.88	0.05	0.8

Structure	# Training Data Sets	# Test Data Sets	Size	DSC Mean	DSC STD	Lower Bound 95% Confidence Interval
Rib	64	17	Large	0.87	0.02	0.84
SeminalVes	236	60	Medium	0.79	0.07	0.67
SpinalCanal	87	22	Large	0.90	0.02	0.87
SpinalCord	1000	24	Medium	0.68	0.09	0.53
Stomach	431	83	Large	0.88	0.07	0.76
Trachea	196	49	Medium	0.87	0.05	0.79
V_Venacava_S	162	41	Medium	0.81	0.06	0.71

These DSC results were compared with state-of-the-art contouring results published in the literature as well as to the Reference Device MIM Contour ProtégéAI (K213976) and were found to be consistent with the state-of-the-art for those structures which had such data available.

The test datasets were independent from that used for training and consisted of 20% of the number of training images sets used as input for the model. For CT structure models there were an average of 700 training and 140 testing image sets. Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing. Among the patients used for CT testing 51.7% were male and 48.3% female. Patient ages range 11-30 : 0.3%, 31-50 : 6.2%, 51-70 : 43.3%, 71-100 : 50.3%. Race 84.0% White, 12.8% Black or African American, 3.2% Other. CT testing data spanned across treatment subgroups most typically found in a radiation therapy treatment clinic with the most common diagnosis being cancers of the Prostate (21%), Breast (21%), Lung (29%), Head and Neck (16%), Other (13%). CT datasets used for testing were acquired using a Philips Big Bore CT simulator with the majority of scans having an average slice thickness of 2mm, In-plane resolution between 1-1.2 mm, and acquisition parameters of 120kVp, 674+/-329 average mAs. Ground truthing of each test data set were generated manually using consensus (NRG/RTOG) guidelines as appropriate by three clinically experienced experts consisting of 2 radiation therapy physicists and 1 radiation dosimetrist.

Sensitivity and specificity for each CT structure model was evaluated on 50 unique patients independent of the training data. 75 structure models had a sensitivity of 100%, 14 models had a sensitivity > 95%, 3 models had a sensitivity > 90%, and 1 model had a sensitivity > 85%.

For CT specificity, 29 structure models had a specificity of 100%, 14 models had a specificity > 90%, 12 models had a specificity > 80%, and the remaining 38 models ranged from 0 to 80%. Note that false positives generally occur when the structure is not actually in the image, and in such cases this issue is mitigated by AutoContour's user-specified structure template system that filters structure results that are not selected by the user.

The MR Testing data set had an average of 81 training image sets and 16 testing image sets. These training sets consisted primarily of glioblastoma and astrocytoma - cases from the Cancer Imaging Archive (TCIA) Glioma data set (Shusharina, N., & Bortfeld, T. (2021). *Glioma Image Segmentation for Radiotherapy: RT targets, barriers to cancer spread, and organs at risk* [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/TCIA.T905-ZQ20). Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing. For MR structure model validation, the testing dataset was acquired at a different institution using a different scanner and sequence parameters (GE Signa HDX, BRAVO sequence) compared to that used by the training dataset (Siemens Skyra MPRAGE sequence). Training and testing data was composed of 56% Male and 44% Female patients with ages ranging from 20-80. No Race or Ethnicity data was provided as a part of this study. The source location is Massachusetts General Hospital, Boston, MA.

MR datasets used for testing had an average slice thickness of 1mm, In-plane resolution between 0.5-1.0 mm, and acquisition parameters of TR=8.9ms, TE=3.2s. Ground truthing of each test data set were generated manually using consensus (NRG/RTOG) guidelines as appropriate by three clinically experienced experts consisting of 2 radiation therapy physicists and 1 radiation dosimetrist. For MR Structure models a mean DSC of 0.67+/-0.08 was found across all structure models.

Structure	Size	Pass Criteria (DSC Mean)	DSC Mean	DSC STD	Lower Bound 95% Confidence Interval
Brainstem	Medium	**0.65**	**0.90**	0.02	0.87
OpticChiasm	Small	**0.50**	**0.53**	0.11	0.35
OpticNrv_L	Small	**0.50**	**0.64**	0.08	0.51
OpticNrv_R	Small	**0.50**	**0.64**	0.08	0.51
Hippocampus_R	Medium	**0.65**	**0.65**	0.09	0.50
Hippocampus_L	Medium	**0.65**	**0.65**	0.09	0.50

Sensitivity and Specificity was evaluated on the 16 validation MR datasets that were not included in the training. All structure models had a sensitivity of 100% and a specificity of >85% in these test cases.

Limitations of AutoContour related to structure contouring performance and limitations of the training data are disclosed in the product labeling. AutoContour also mitigates risk of incorrect contours being propagated into a treatment plan through a review process that requires users to review every slice and approve the structure prior to being able to export it to a treatment planning system.

Validation testing of the AutoContour RADAC V2 device supports substantial equivalence to the predicate device AutoContour RADAC (K200323) and shows that the device performs as well as the reference device MIM Contour ProtégéAI (K213976) in automatic segmentation.

Mechanical and Acoustic Testing Not Applicable (Standalone Software)
Not Applicable (Standalone Software)

Animal Study
No animal studies were conducted using the Subject Device, AutoContour.

Clinical Studies
No clinical studies were conducted using the Subject Device, AutoContour

5.9. Conclusion
Based on this Discussion and Testing and Performance Data, the subject device is determined to be as safe and effective as its predicate device AutoContour RADAC (K200323) and performs as well in automatic segmentation performance as the reference device, MIM Contour ProtégéAI (K213976).