Radformation, Inc.   April 14, 2023
℅ Kurt Sysock
Co-founder/CEO
335 Madison Avenue, 4th floor
NEW YORK NY 10017

Re: K230685
     Trade/Device Name: AutoContour Model RADAC V3
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Medical Image Management And Processing System
     Regulatory Class: Class II
     Product Code: QKB
     Dated: March 9, 2023
     Received: March 13, 2023

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,

Lora D. Weidner -S
Digitally signed by Lora D. Weidner -S
Date: 2023.04.14 10:50:08 -04'00'

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

510(k) Number *(if known)*
K230685

Device Name
AutoContour Model RADAC V3

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.

AutoContour Software

Radformation, Inc.

Special 510(k) Summary

Table of Contents

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	03/09/2023

5.2. Device Information

Table 2 : Device Information	
Trade Name:	AutoContour Model RADAC V3
Common Name:	AutoContour, AutoContouring, AutoContour Agent, AutoContour Cloud Server
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 Model RADAC V3 (Subject Device) makes use of its prior submissions - AutoContour Model RADAC V2 (K220598) - as the Predicate Device.

5.4. Device Description

As with AutoContour Model RADAC V2, the AutoContour Model RADAC V3 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 Model RADAC V3 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

The Subject Device, AutoContour Model RADAC V3 makes use of AutoContour Model RADAC V2 (K220598) as the Predicate Device for substantial equivalence comparison. The functionality and technical components of this prior submission remain unchanged in AutoContour Model RADAC V3. This submission is intended to build on the technological characteristics of the 510(k) cleared AutoContour Model RADAC V2 pertaining to new structure models for both CT and MRI.

5.6.1. Updates vs. AutoContour (K220598)

The updated submission expands the use of machine-learning based contouring to include additional organs and volumes of Interest found in MR and CT image types.

Table 3: Technological Characteristics AutoContour Model RADAC V3 vs. AutoContour Model RADAC V2 (K220598)		
Characteristic	Subject Device: AutoContour Model RADAC V3	Predicate Device: AutoContour Model RADAC V2 (K220598)
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.	AutoContour is intended to assist radiation treatment planners in contouring and reviewing structures within medical images in preparation for radiation therapy treatment planning.
Design: Image registration	Manual and Automatic Rigid registration. Automatic Deformable Registration	Manual and Automatic Rigid registration. Automatic Deformable 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 or MR input for contouring or registration/fusion. PET/CT input for 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 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 ● **A_Pulmonary** ● Bladder ● **Bladder_F** ● Bone_Ilium_L ● Bone_Ilium_R ● Bone_Mandible ● **Bone_Pelvic** ● **Bone_Skull** ● **Bone_Sternum** ● **Bowel** ● Bowel_Bag ● **Bowel_Large** ● **Bowel_Small** ● BrachialPlex_L ● BrachialPlex_R ● Brain ● Brainstem ● Breast_L ● Breast_R ● Bronchus ● **BuccalMucosa** ● Carina ● CaudaEquina ● Cavity_Oral ● **Cavity_Oral_Ext** ● **Chestwall_L** ● **Chestwall_OAR** ● **Chestwall_R** ● **Chestwall_RC_L** ● **Chestwall_RC_R** ● Cochlea_L ● Cochlea_R ● **Colon_Sigmoid** ● **Cornea_L** ● **Cornea_R** ● **Duodenum** ● Ear_Internal_L ● Ear_Internal_R ● Esophagus ● External ● Eye_L ● Eye_R	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 ● 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

	- **Femur_Head_L** - **Femur_Head_R** - Femur_L - Femur_R - Femur_RTOG_L - Femur_RTOG_R - **GallBladder** - **Genitals_F** - **Genitals_M** - Glnd_Lacrimal_L - Glnd_Lacrimal_R - Glnd_Submand_L - Glnd_Submand_R - Glnd_Thyroid - HDR_Cylinder - Heart - **Hippocampus_L** - **Hippocampus_R** - Humerus_L - Humerus_R - Kidney_L - Kidney_R - Kidney_Outer_L - Kidney_Outer_R - Larynx - **Larynx_Glottic** - **Larynx_NRG** - **Larynx_SG** - Lens_L - Lens_R - Lips - Liver - LN_Ax_L - **LN_Ax_L1_L** - **LN_Ax_L1_R** - **LN_Ax_L2_L** - **LN_Ax_L2_L3_L** - **LN_Ax_L2_L3_R** - **LN_Ax_L2_R** - **LN_Ax_L3_L** - **LN_Ax_L3_R** - LN_Ax_R - LN_IMN_L - LN_IMN_R - **LN_IMN_RC_L** - **LN_IMN_RC_R** - **LN_Inguinofem_L** - **LN_Inguinofem_R** - LN_Neck_IA - LN_Neck_IB-V_L - LN_Neck_IB-V_R	- 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 - Trachea - V_Venacava_S MR Models: - OpticChiasm - OpticNrv_L

	• LN_Neck_II_L • LN_Neck_II_R • LN_Neck_II-IV_L • LN_Neck_II-IV_R • **LN_Neck_II-V_L** • **LN_Neck_II-V_R** • LN_Neck_III_L • LN_Neck_III_R • LN_Neck_IV_L • LN_Neck_IV_R • **LN_Neck_V_L** • **LN_Neck_V_R** • LN_Neck_VIA • LN_Neck_VIIA_L • LN_Neck_VIIA_R • LN_Neck_VIIB_L • LN_Neck_VIIB_R • **LN_Paraaortic** • LN_Pelvics • **LN_Pelvic_NRG** • LN_Sclav_L • LN_Sclav_R • **LN_Sclav_RADCOMP_L** • **LN_Sclav_RADCOMP_R** • **Lobe_Temporal_L** • **Lobe_Temporal_R** • Lung_L • Lung_R • **Macula_L** • **Macula_R** • Marrow_Ilium_L • Marrow_Ilium_R • Musc_Constrict • **Nipple_L** • **Nipple_R** • OpticChiasm • OpticNrv_L • OpticNrv_R • **Pancreas** • Parotid_L • Parotid_R • PenileBulb • **Pericardium** • Pituitary • Prostate • Rectum • **Rectum_F** • **Retina_L** • **Retina_R** • Rib • **Rib_L**	• OpticNrv_R • Brainstem • Hippocampus_L • Hippocampus_R

	Rib_R - SeminalVes - SpinalCanal - SpinalCord **Spleen** - Stomach - Trachea **UteroCervix** **V_Venacava_I** - V_Venacava_S - VB **VB_C1** **VB_C2** **VB_C3** **VB_C4** **VB_C5** **VB_C6** **VB_C7** **VB_L1** **VB_L2** **VB_L3** **VB_L4** **VB_L5** **VB_T01** **VB_T02** **VB_T03** **VB_T04** **VB_T05** **VB_T06** **VB_T07** **VB_T08** **VB_T09** **VB_T10** **VB_T11** **VB_T12** MR Models: - Brainstem **Cerebellum** **Eye_L** **Eye_R** **Glnd_Prostate** - Hippocampus_L - Hippocampus_R **Hypo_True** **Hypothalamus** - OpticChiasm - OpticNrv_L - OpticNrv_R **OpticTract_L** **OpticTract_R**	

	● **Pituitary** ● **Prostate** ● **SeminalVes**	
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.	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.

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

5.7. Discussion of differences

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:
- **New CT Models:**
  Compared with the Predicate Device, AutoContour Model RADAC V3 supports contouring **90** 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) very similar CNN architecture was used to train these new CT models
  (b) all new models passed the same DSC test protocol criteria that was applied to the models in the predicate device for similar structure sizes
  (c) the same risk mitigations that have been applied to the predicate device models have also been applied to all new models
    - A_Pulmonary
    - Bladder_F
    - Bone_Pelvic
    - Bone_Skull
    - Bone_Sternum
    - Bowel
    - Bowel_Large
    - Bowel_Small

- ○ BuccalMucosa
- ○ Cavity_Oral_Ext
- ○ Chestwall_L
- ○ ChestWall_OAR
- ○ Chestwall_R
- ○ Chestwall_RC_L
- ○ Chestwall_RC_R
- ○ Colon_Sigmoid
- ○ Cornea_L
- ○ Cornea_R
- ○ Duodenum
- ○ Femur_Head_L
- ○ Femur_Head_R
- ○ GallBladder
- ○ Genitals_F
- ○ Genitals_M
- ○ Hippocampus_L
- ○ Hippocampus_R
- ○ Larynx_Glottic
- ○ Larynx_NRG
- ○ Larynx_SG
- ○ LN_Ax_L1_L
- ○ LN_Ax_L1_R
- ○ LN_Ax_L2_L
- ○ LN_Ax_L2_L3_L
- ○ LN_Ax_L2_L3_R
- ○ LN_Ax_L2_R
- ○ LN_Ax_L3_L
- ○ LN_Ax_L3_R
- ○ LN_IMN_RC_L
- ○ LN_IMN_RC_R
- ○ LN_Inguinofem_L
- ○ LN_Inguinofem_R
- ○ LN_Neck_II-V_L
- ○ LN_Neck_II-V_R
- ○ LN_Neck_V_L
- ○ LN_Neck_V_R
- ○ LN_Paraaortic
- ○ LN_Pelvics_NRG
- ○ LN_Sclav_RC_L
- ○ LN_Sclav_RC_R
- ○ Lobe_Temporal_L
- ○ Lobe_Temporal_R
- ○ Macula_L

- ○ Macula_R
- ○ Nipple_L
- ○ Nipple_R
- ○ Pancreas
- ○ Pericardium
- ○ Rectum_F
- ○ Retina_L
- ○ Retina_R
- ○ Rib_L
- ○ Rib_R
- ○ Spleen
- ○ UteroCervix
- ○ V_Venacava_I
- ○ VB
- ○ VB_C1
- ○ VB_C2
- ○ VB_C3
- ○ VB_C4
- ○ VB_C5
- ○ VB_C6
- ○ VB_C7
- ○ VB_L1
- ○ VB_L2
- ○ VB_L3
- ○ VB_L4
- ○ VB_L5
- ○ VB_T01
- ○ VB_T02
- ○ VB_T03
- ○ VB_T04
- ○ VB_T05
- ○ VB_T06
- ○ VB_T07
- ○ VB_T08
- ○ VB_T09
- ○ VB_T10
- ○ VB_T11
- ○ VB_T12
- **New MR Models:**
  Compared with the Predicate Device, AutoContour Model RADAC V3 supports contouring **11** new models on MR 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) very similar CNN architecture was used to train these new CT models
(b) all new models passed the same DSC test protocol criteria that was applied to the models in the predicate device for similar structure sizes
(c) the same risk mitigations that have been applied to the predicate device models have also been applied to all new models

- Cerebellum
- Eye_L
- Eye_R
- Glnd_Prostate
- Hypo_True
- Hypothalamus
- OpticTract_L
- OpticTract_R
- Pituitary
- Prostate
- SeminalVes

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

Summary
    As with the Predicate Device, no clinical trials were performed for AutoContour Model RADAC V3. Non-clinical tests were performed according to Radformation's AutoContour Complete Test Protocol and Report, which demonstrates that AutoContour Model RADAC V3 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.

<u>Description of Changes to Test Protocol</u>

Changes to the testing protocol between AutoContour RADAC V2 and RADAC V3 were made to improve reviewer independence and the validation dataset for the intended population. These changes better demonstrate the ability of the structure model outputs in assisting the user to contour more efficiently as per AutoContour's Indications for Use.

We do not feel that the changes are a significant deviation from the past report as the primary passing criteria is still based on the same minimum mean DSC score and a qualitative review of the structure model output. For RADAC V3 structure models, additional DSC and qualitative review validation was performed on image data that was acquired uniquely from the data used for training. Additionally, independent reviewers (not employed by Radformation) were used to evaluate the clinical appropriateness of structure models as they would be evaluated for the purposes of treatment planning. This external review was performed as a replacement to intraobserver variability testing done with the RADAC V2 structure models as it better quantified the usefulness of the structure model outputs in an unbiased clinical setting.

The RADAC V3 test protocol also adds a section that addresses the validation of any existing structure models that were approved within previous releases of the software (RADAC V2). This regression testing was added as a way to confirm that updates made to the software made for any new releases do not affect the output of any previously approved models.The addition of this test is not significant to the testing of the new structure models as it only confirms that no structure output "drift" has occurred between version releases.

<u>Testing Summary</u>

Mean Dice Similarity Coefficient (DSC) was used to validate the accuracy of structure model outputs when tested on image data sequestered from the original training data population.The test datasets were independent from those used for training and consisted of approximately 10% of the number of training image sets used as input for the model. For CT structure models there were an average of 373 training and 50 testing image sets. Among the patients used for CT training and 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 datasets 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%). Images 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.

Structure models were categorized into three size categories as DSC metrics can be sensitive to structure volume. A structure would pass initial validation if the mean

DSC exceeded 0.8 for Large volume structures (eg. Bladder, Spleen) 0.65 for Medium volume structures (eg. gallbladder, duodenum) and 0.5 for Small structures (eg Cornea, Retina). For CT Structure models large, medium and small structures resulted in a mean DSC of 0.88+/-0.06, 0.88+/-0.08, and 0.75+/-0.12 respectively. A full summary of the CT structure DSC is available below:

Table 4: CT Training Data Results for AutoContour Model RADAC V3							
CT Structure	Size	Pass Criteria	# of Training Sets	# of Testing Sets	DSC (Avg)	DSC Std Dev	Lower Bound 95% Confidence Interval
A_Pulmonary	Medium	0.65	169	43	0.88	0.03	0.83
Bladder_F	Large	0.8	252	63	0.94	0.03	0.89
Bone_Pelvic	Large	0.8	201	51	0.94	0.01	0.92
Bone_Skull	Large	0.8	80	20	0.92	0.01	0.90
Bone_Sternum	Medium	0.65	80	20	0.9	0.02	0.87
Bowel	Medium	0.65	705	45	0.93	0.08	0.80
Bowel_Large	Medium	0.65	805	52	0.89	0.17	0.61
Bowel_Small	Medium	0.65	705	45	0.93	0.05	0.85
BuccalMucosa	Medium	0.65	392	98	0.7	0.05	0.62
Cavity_Oral_Ext	Medium	0.65	392	98	0.94	0.02	0.91
Chestwall_L	Large	0.8	79	20	0.9	0.03	0.85
Chestwall_R	Large	0.8	79	20	0.9	0.03	0.85
Chestwall_OAR	Large	0.8	118	30	0.9	0.03	0.85
Chestwall_RC_L	Large	0.8	80	20	0.91	0.04	0.84
Chestwall_RC_R	Large	0.8	80	20	0.91	0.04	0.84
Colon_Sigmoid	Medium	0.65	392	98	0.66	0.28	0.20
Cornea_L	Small	0.5	N/A*	N/A*	N/A*	N/A*	N/A
Cornea_R	Small	0.5	N/A*	N/A*	N/A*	N/A*	N/A
Duodenum	Medium	0.65	659	44	0.88	0.16	0.62
Femur_Head_L	Medium	0.65	160	40	0.95	0.04	0.88
Femur_Head_R	Medium	0.65	160	40	0.95	0.04	0.88
Gallbladder	Medium	0.65	512	32	0.96	0.03	0.91
Genitals_F	Large	0.8	233	59	0.92	0.02	0.89
Genitals_M	Large	0.8	173	44	0.93	0.03	0.88
Hippocampus_L	Medium	0.65	226	57	0.67	0.1	0.51
Hippocampus_R	Medium	0.65	226	57	0.67	0.1	0.51

Larynx_Glottic	Medium	0.65	438	110	0.81	0.04	0.74
Larynx_NRG	Medium	0.65	449	113	0.8	0.04	0.73
Larynx_SG	Medium	0.65	413	104	0.78	0.04	0.71
LN_Ax_L1_L	Large	0.8	437	110	0.81	0.06	0.71
LN_Ax_L1_R	Large	0.8	437	110	0.81	0.06	0.71
LN_Ax_L2_L	Medium	0.65	203	51	0.79	0.04	0.72
LN_Ax_L2_L3_L	Medium	0.65	437	110	0.82	0.06	0.72
LN_Ax_L2_L3_R	Medium	0.65	437	110	0.82	0.06	0.72
LN_Ax_L2_R	Medium	0.65	203	51	0.79	0.04	0.72
LN_Ax_L3_L	Medium	0.65	203	51	0.74	0.07	0.62
LN_Ax_L3_R	Medium	0.65	203	51	0.74	0.07	0.62
LN_IMN_RC_L	Medium	0.65	100	25	0.78	0.05	0.70
LN_IMN_RC_R	Medium	0.65	100	25	0.78	0.05	0.70
LN_Inguinofem_L	Large	0.8	310	78	0.85	0.05	0.77
LN_Inguinofem_R	Large	0.8	310	78	0.85	0.05	0.77
LN_Neck_II-V_L	Medium	0.65	323	81	0.86	0.03	0.81
LN_Neck_II-V_R	Medium	0.65	323	81	0.86	0.03	0.81
LN_Neck_V_L	Medium	0.65	267	67	0.8	0.08	0.67
LN_Neck_V_R	Medium	0.65	267	67	0.8	0.08	0.67
LN_Paraaortic	Large	0.8	200	50	0.89	0.04	0.82
LN_Pelvics_NRG	Large	0.8	149	38	0.88	0.02	0.85
LN_Sclav_RC_L	Medium	0.65	200	51	0.8	0.04	0.73
LN_Sclav_RC_R	Medium	0.65	200	51	0.8	0.04	0.73
Lobe_Temporal_L	Large	0.8	174	44	0.88	0.03	0.83
Lobe_Temporal_R	Large	0.8	174	44	0.88	0.03	0.83
Macula_L	Small	0.5	120	31	0.64	0.1	0.48
Macula_R	Small	0.5	120	31	0.64	0.1	0.48
Nipple_L	Medium	0.65	91	23	0.74	0.1	0.58
Nipple_R	Medium	0.65	91	23	0.74	0.1	0.58
Pancreas	Medium	0.65	706	45	0.92	0.1	0.76
Pericardium	Large	0.8	160	41	0.94	0.02	0.91
Rectum_F	Medium	0.65	252	64	0.91	0.02	0.88
Retina_L	Small	0.5	N/A*	N/A*	N/A*	N/A*	N/A*
Retina_R	Small	0.5	N/A*	N/A*	N/A*	N/A*	N/A*
Rib_L	Large	0.8	N/A*	N/A*	N/A*	N/A*	N/A*

Rib_R	Large	0.8	N/A*	N/A*	N/A*	N/A*	N/A*
Spleen	Large	0.8	160	41	0.92	0.08	0.79
UteroCervix	Medium	0.65	143	36	0.81	0.11	0.63
V_Venacava_I	Medium	0.65	399	100	0.81	0.09	0.66
VB	Large	0.8	1051	64	0.99	0.01	0.98
VB_C1	Medium	0.65	196	14	0.90	0.25	0.48
VB_C2	Medium	0.65	202	13	0.99	0.01	0.97
VB_C3	Medium	0.65	214	14	0.97	0.03	0.92
VB_C4	Medium	0.65	234	15	0.90	0.24	0.51
VB_C5	Medium	0.65	328	20	0.89	0.21	0.55
VB_C6	Medium	0.65	520	33	0.87	0.24	0.49
VB_C7	Medium	0.65	651	36	0.98	0.01	0.95
VB_L1	Large	0.8	731	49	0.97	0.09	0.82
VB_L2	Large	0.8	650	44	0.99	0.03	0.93
VB_L3	Large	0.8	582	44	0.99	0.03	0.93
VB_L4	Large	0.8	569	44	0.99	0.01	0.97
VB_L5	Large	0.8	550	43	0.99	0.02	0.95
VB_T01	Medium	0.65	663	37	0.98	0.01	0.96
VB_T02	Medium	0.65	682	38	0.96	0.12	0.76
VB_T03	Medium	0.65	700	38	0.96	0.14	0.73
VB_T04	Medium	0.65	695	39	0.95	0.16	0.68
VB_T05	Medium	0.65	687	39	0.97	0.08	0.84
VB_T06	Medium	0.65	682	36	0.97	0.06	0.86
VB_T07	Medium	0.65	686	39	0.94	0.16	0.69
VB_T08	Medium	0.65	729	45	0.96	0.14	0.73
VB_T09	Medium	0.65	778	49	0.98	0.04	0.92
VB_T10	Medium	0.65	803	49	0.97	0.09	0.82
VB_T11	Medium	0.65	814	48	0.98	0.07	0.86
VB_T12	Medium	0.65	795	50	0.97	0.13	0.75

*N/A: Structures are generated based on a post-processing/boolean operation from previously released structure models (Eye, Rib) rather than generated from a CNN model. Quantitative and Qualitative testing for these structures is still performed in the external clinical testing below to validate appropriate contour generation and clinical acceptability of these derived structure models.

Additional external clinical testing was performed in order to validate the accuracy of the models on image sets acquired that were unique to the training datasets. Publically available CT datasets from The Cancer Imaging Archive (TCIA archive) were used and both AutoContour and manually added ground truth contours following the

same structure guidelines used for structure model training were added to the image sets.

Table 5: CT External Clinical Dataset References		
Model Group	**Data Source ID**	**Data Citation**
CT Pelvis	TCIA - Pelvic-Ref	Afua A. Yorke, Gary C. McDonald, David Solis Jr., Thomas Guerrero. (2019) Pelvic Reference Data. The Cancer Imaging Archive. DOI: 10.7937/TCIA.2019.woskq5oo
CT Head and Neck	TCIA - Head-Neck-PET-CT	Martin Vallières, Emily Kay-Rivest, Léo Jean Perrin, Xavier Liem, Christophe Furstoss, Nader Khaouam, Phuc Félix Nguyen-Tan, Chang-Shu Wang, Khalil Sultanem. (2017). Data from Head-Neck-PET-CT. The Cancer Imaging Archive. doi: 10.7937/K9/TCIA.2017.8oje5q00
CT Abdomen	TCIA - Pancreas-CT-CB	Hong, J., Reyngold, M., Crane, C., Cuaron, J., Hajj, C., Mann, J., Zinovoy, M., Yorke, E., LoCastro, E., Apte, A. P., & Mageras, G. (2021). Breath-hold CT and cone-beam CT images with expert manual organ-at-risk segmentations from radiation treatments of locally advanced pancreatic cancer [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/TCIA.ESHQ-4D90
CT Thorax:	TCIA - NSCLC	Aerts, H. J. W. L., Wee, L., Rios Velazquez, E., Leijenaar, R. T. H., Parmar, C., Grossmann, P., Carvalho, S., Bussink, J., Monshouwer, R., Haibe-Kains, B., Rietveld, D., Hoebers, F., Rietbergen, M. M., Leemans, C. R., Dekker, A., Quackenbush, J., Gillies, R. J., Lambin, P. (2019). Data From NSCLC-Radiomics [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2015.PF0M9REI
CT Thorax	TCIA - LCTSC	Yang, J., Sharp, G., Veeraraghavan, H., Van Elmpt, W., Dekker, A., Lustberg, T., & Gooding, M. (2017). Data from Lung CT Segmentation Challenge (Version 3) [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/K9/TCIA.2017.3R3FVZ08

DSC values were calculated between ground truth contour data and AutoContour structures and rated on the same DSC passing criteria used for the Training DSC validation. All structures passed the minimum DSC criteria for small, medium and large structures with an mean DSC of 0.79+/-0.11, 0.83+/-0.12, and 0.90+/-0.09 respectively: Additionally, the qualitative clinical appropriateness of AutoContour structures generated on these scans was graded by clinical experts. Autocontour structures were graded on a scale from 1 to 5 where 5 refers to contour requiring no additional edits, and 1 refers to a score in which full manual re-contour of the structure would be required. An average score >= 3 was used to determine whether a structure model would ultimately be beneficial clinically. An average rating of 4.5 was found across all CT structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use.

CT Structure	Size	Pass Criteria	# Testings Sets	Average DSC	Average DSC Std. Dev	Lower Bound 95% Confidence Interval	External Reviewer Average Rating (1-5)

Table 6: CT External Reviewer Results for AutoContour Model RADAC V3

CT Structure	Size	Pass Criteria	# Testings Sets	Average DSC	Average DSC Std. Dev	Lower Bound 95% Confidence Interval	External Reviewer Average Rating (1-5)
A_Pulmonary	Medium	0.65	20	0.93	0.02	0.89	4.6
Bladder_F	Large	0.8	20	0.87	0.22	0.52	4.8
Bone_Pelvic	Large	0.8	41	0.93	0.04	0.86	4.4
Bone_Skull	Large	0.8	23	0.98	0.01	0.97	4.5
Bone_Sternum	Medium	0.65	20	0.92	0.03	0.88	4.8
Bowel	Medium	0.65	46	0.86	0.07	0.75	4.3
Bowel_Large	Medium	0.65	46	0.81	0.07	0.70	4.1
Bowel_Small	Medium	0.65	46	0.77	0.07	0.66	4.0
BuccalMucosa	Medium	0.65	23	0.68	0.10	0.51	4.2
Cavity_Oral_Ext	Medium	0.65	23	0.97	0.01	0.95	4.9
Chestwall_L	Large	0.8	20	0.88	0.10	0.71	4.4
Chestwall_R	Large	0.8	20	0.90	0.05	0.82	4.4
Chestwall_OAR	Large	0.8	20	0.94	0.03	0.89	4.8
Chestwall_RC_L	Large	0.8	20	0.91	0.05	0.83	5.0
Chestwall_RC_R	Large	0.8	20	0.91	0.03	0.85	5.0
Colon_Sigmoid	Medium	0.65	40	0.68	0.20	0.35	4.2
Cornea_L	Small	0.5	23	0.80	0.04	0.73	4.8
Cornea_R	Small	0.5	23	0.79	0.06	0.69	4.8
Duodenum	Medium	0.65	25	0.72	0.15	0.48	4.8
Femur_Head_L	Medium	0.65	41	0.94	0.06	0.85	4.9
Femur_Head_R	Medium	0.65	41	0.93	0.07	0.82	4.8
Gallbladder	Medium	0.65	21	0.86	0.05	0.78	4.8
Genitals_F	Large	0.8	20	0.89	0.04	0.83	4.5

Genitals_M	Large	0.8	21	0.96	0.03	0.92	4.7
Hippocampus_L	Medium	0.65	23	0.85	0.08	0.71	4.6
Hippocampus_R	Medium	0.65	23	0.87	0.08	0.74	4.6
Larynx_Glottic	Medium	0.65	23	0.83	0.10	0.66	5.0
Larynx_NRG	Medium	0.65	23	0.93	0.05	0.85	4.7
Larynx_SG	Medium	0.65	23	0.81	0.10	0.65	4.8
LN_Ax_L1_L	Large	0.8	20	0.86	0.10	0.70	4.4
LN_Ax_L1_R	Large	0.8	20	0.87	0.08	0.74	4.3
LN_Ax_L2_L	Medium	0.65	20	0.74	0.05	0.65	4.1
LN_Ax_L2_L3_L	Medium	0.65	20	0.86	0.07	0.75	4.3
LN_Ax_L2_L3_R	Medium	0.65	20	0.87	0.04	0.80	4.5
LN_Ax_L2_R	Medium	0.65	20	0.75	0.05	0.67	4.0
LN_Ax_L3_L	Medium	0.65	20	0.73	0.09	0.57	4.2
LN_Ax_L3_R	Medium	0.65	20	0.75	0.08	0.61	4.2
LN_IMN_RC_L	Medium	0.65	20	0.84	0.09	0.68	3.9
LN_IMN_RC_R	Medium	0.65	19	0.81	0.14	0.58	3.9
LN_Inguinofem_L	Large	0.8	40	0.91	0.09	0.77	4.1
LN_Inguinofem_R	Large	0.8	38	0.90	0.08	0.77	4.1
LN_Neck_II-V_L	Medium	0.65	23	0.98	0.01	0.97	4.5
LN_Neck_II-V_R	Medium	0.65	23	0.98	0.01	0.96	4.5
LN_Neck_V_L	Medium	0.65	23	0.79	0.04	0.72	4.6
LN_Neck_V_R	Medium	0.65	23	0.76	0.07	0.65	4.4
LN_Paraaortic	Large	0.8	23	0.88	0.05	0.79	4.6
LN_Pelvics_NRG	Medium	0.65	41	0.79	0.18	0.48	4.4
LN_Sclav_RC_L	Medium	0.65	20	0.72	0.16	0.45	4.3
LN_Sclav_RC_R	Medium	0.65	20	0.70	0.14	0.47	4.2

Lobe_Temporal_L	Large	0.8	23	0.87	0.05	0.79	4.6
Lobe_Temporal_R	Large	0.8	23	0.88	0.05	0.81	4.6
Macula_L	Small	0.5	23	0.70	0.26	0.27	5.0
Macula_R	Small	0.5	23	0.72	0.23	0.34	5.0
Nipple_L	Medium	0.65	35	0.78	0.11	0.60	5.0
Nipple_R	Medium	0.65	38	0.78	0.17	0.50	5.0
Pancreas	Medium	0.65	25	0.71	0.15	0.47	4.1
Pericardium	Large	0.8	20	0.99	0.00	0.98	4.7
Rectum_F	Medium	0.65	20	0.90	0.09	0.76	4.2
Retina_L	Small	0.5	23	0.88	0.03	0.83	5.0
Retina_R	Small	0.5	23	0.88	0.03	0.84	5.0
Rib_L	Large	0.8	20	0.85	0.04	0.78	4.9
Rib_R	Large	0.8	20	0.85	0.04	0.79	4.8
Spleen	Large	0.8	24	0.95	0.07	0.84	4.9
Stomach (Update)	Large	0.8	25	0.90	0.06	0.80	4.9
CaudaEquina (Update)	Medium	0.65	42	0.88	0.06	0.77	4.5
UteroCervix	Medium	0.65	14	0.74	0.23	0.36	3.8
V_Venacava_I	Medium	0.65	41	0.81	0.08	0.68	4.8
VB	Large	0.8	63	0.96	0.03	0.91	4.4
VB_C1	Medium	0.65	23	0.95	0.02	0.92	4.6
VB_C2	Medium	0.65	24	0.96	0.02	0.92	4.7
VB_C3	Medium	0.65	26	0.93	0.10	0.77	4.5
VB_C4	Medium	0.65	33	0.87	0.20	0.54	4.6
VB_C5	Medium	0.65	40	0.87	0.16	0.61	4.6
VB_C6	Medium	0.65	42	0.90	0.07	0.78	4.6
VB_C7	Medium	0.65	42	0.93	0.04	0.87	4.8

VB_L1	Large	0.8	32	0.88	0.22	0.53	4.7
VB_L2	Large	0.8	25	0.89	0.21	0.55	4.7
VB_L3	Large	0.8	20	0.92	0.19	0.60	4.9
VB_L4	Large	0.8	20	0.93	0.21	0.58	4.8
VB_L5	Large	0.8	20	0.92	0.20	0.60	4.4
VB_T01	Medium	0.65	43	0.94	0.13	0.72	4.7
VB_T02	Medium	0.65	43	0.95	0.05	0.86	4.5
VB_T03	Medium	0.65	43	0.93	0.12	0.73	4.9
VB_T04	Medium	0.65	43	0.93	0.14	0.69	4.6
VB_T05	Medium	0.65	44	0.90	0.20	0.58	4.6
VB_T06	Medium	0.65	43	0.88	0.22	0.51	4.7
VB_T07	Medium	0.65	37	0.83	0.29	0.36	4.7
VB_T08	Medium	0.65	27	0.79	0.33	0.25	4.7
VB_T09	Medium	0.65	23	0.79	0.32	0.26	4.7
VB_T10	Medium	0.65	23	0.81	0.31	0.29	4.7
VB_T11	Medium	0.65	24	0.82	0.31	0.30	4.7
VB_T12	Medium	0.65	31	0.86	0.24	0.46	4.8

The MR training data set used for initial testing of the Brain models (Cerebellum, Hypothalamus, Hypo_True, OpticTract_L, OpticTract_R, Pituitary, Eye_L, Eye_R) had an average of 274 training image sets and 92 testing image sets and were acquired from the Cancer Imaging Archive GLIS-RT dataset. These data sets consisted primarily of glioblastoma and astrocytoma patients. Images were acquired on either a GE Signa HDxT (3T) or Siemens Skyra (3T) scanner and had an average slice thickness of 1mm, In-plane resolution between 0.5-1.0 mm, and acquisition parameters of TR=2.3-8.9ms, TE=3.0-3.2s.

The MR training data used for initial testing of the MR Pelvis models (Prostate, Glnd_Prostate, and SeminalVes) was taken from the Cancer Imaging Archive Prostate-MRI-US-Biopsy dataset which consisted patients with a of suspicion of prostate cancer due to elevated PSA and/or suspicious imaging findings. The images used were T2-Axial image sets acquired on a 3T Siemens Skyra scanner. The majority of pulse

sequences used are 3D T2:SPC, with TR/TE 2200/203, Matrix/FOV 256 × 205/14 × 14 cm, and 1.5mm slice spacing.

Table 7: MR Initial Testing Dataset References		
Model Group	**Data Source ID**	**Data Citation**
MR Brain	MR - Renown	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
MR Pelvis	Gold Atlas Pelvis	Natarajan, S., Priester, A., Margolis, D., Huang, J., & Marks, L. (2020). Prostate MRI and Ultrasound With Pathology and Coordinates of Tracked Biopsy (Prostate-MRI-US-Biopsy) [Data set]. The Cancer Imaging Archive. DOI: 10.7937/TCIA.2020.A61IOC1A

Datasets used for testing were removed from the training dataset pool before model training began, and used exclusively for testing.

Ground truthing of each test data set was 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 training DSC of 0.87+/-0.07 was found for medium models and 0.74+/-0.07 for small models.

Table 8: MR Training Data Results for AutoContour Model RADAC V3					
MR Models	**Size**	**Pass Criteria**	**DSC (Avg)**	**DSC Std Dev (Avg)**	**Lower Bound 95% Confidence Interval**
Cerebellum	Medium	0.65	0.93	0.01	0.91
Glnd_Prostate	Medium	0.65	0.87	0.04	0.80
Hypothalamus	Small	0.50	0.79	0.04	0.72
Hypo_True	Small	0.50	0.71	0.06	0.61
OpticTract_L	Small	0.50	0.72	0.08	0.59
OpticTract_R	Small	0.50	0.72	0.08	0.59
Pituitary	Small	0.50	0.75	0.11	0.57
Prostate	Medium	0.65	0.89	0.03	0.84
SeminalVes	Medium	0.65	0.74	0.13	0.53
Eye_L	Medium	0.65	0.90	0.10	0.74
Eye_R	Medium	0.65	0.90	0.10	0.74

Additional external clinical testing was performed in order to validate the accuracy of the models on image sets acquired that were unique to the training datasets.

Table 9: MR External Clinical Dataset References		
Model Group	Data Source ID	Data Citation
MR Brain	MR - Renown	N/A
MR Pelvis	Gold Atlas Pelvis	Nyholm, Tufve, Stina Svensson, Sebastian Andersson, Joakim Jonsson, Maja Sohlin, Christian Gustafsson, Elisabeth Kjellén, et al. 2018. "MR and CT Data with Multi Observer Delineations of Organs in the Pelvic Area - Part of the Gold Atlas Project." *Medical Physics* 12 (10): 3218–21. doi:10.1002/mp.12748.

For the Brain models, datasets acquired via data-use agreement from a clinical partner were acquired containing 20 MR T1 Ax post (BRAVO) image scans acquired with a GE MR750w scanner. Images had an average slice thickness of 1.6mm, In-plane resolution between 0.94 mm, and acquisition parameters of TR=5.98ms, TE=96.8s. Data for testing of the MR Pelvis structure models were acquired from a publicly available Gold Atlas Data set which contained 19 images of patients with prostate or rectal cancer. Images were acquired on a GE DISCOVERY MR750w (Ax T2 FRFSE) with in-plane resolution of 0.9mm, Slice thickness of 2.5mm, TR=5.988s and TE=96.8ms.

DSC values were calculated between ground truth contour data and AutoContour structures and rated on the same DSC passing criteria as was used for the training DSC validation. All structures passed the minimum DSC criteria for small and medium structures with a mean DSC of 0.74+/-0.07, 0.87+/-0.07 respectively: Additionally, the qualitative clinical appropriateness of AutoContour structures generated on these scans was graded by clinical experts. Autocontour structures were graded on a scale from 1 to 5 where 5 refers to contour requiring no additional edits, and 1 refers to a score in which full manual re-contour of the structure would be required. An average score >= 3 was used to determine whether a structure model would ultimately be beneficial clinically. An average rating of 4.4 was found across all MR structure models demonstrating that only minor edits would be required in order to make the structure models acceptable for clinical use.

Table 10: MR External Reviewer Results for AutoContour Model RADAC V3							
MR Models	Size	Pass Criteria	# External Test Data Sets	Average DSC	Average DSC Std. Dev	Lower Bound 95% Confidence Interval	External Reviewer Average Rating (1-5)
Cerebellum	Medium	0.65	20	0.93	0.01	0.91	4
Glnd_Prostate	Medium	0.65	18	0.87	0.04	0.80	4.3
Hypothalamus	Small	0.50	20	0.79	0.04	0.72	4.2
Hypo_True	Small	0.50	19	0.71	0.06	0.61	4.3
OpticTract_L	Small	0.50	20	0.72	0.08	0.59	4.4
OpticTract_R	Small	0.50	19	0.72	0.08	0.59	4.5
Pituitary	Small	0.50	19	0.75	0.11	0.57	4.2
Prostate	Medium	0.65	19	0.89	0.03	0.84	4.2
SeminalVes	Medium	0.65	19	0.74	0.13	0.53	4.2
Eye_L	Medium	0.65	19	0.90	0.10	0.74	4.9
Eye_R	Medium	0.65	20	0.90	0.10	0.74	4.9

Validation testing of the AutoContour application demonstrated that the software meets user needs and intended uses of the application.

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
AutoContour Model RADAC V3 is deemed substantially equivalent to the Predicate Device, AutoContour Model RADAC V2 (K220598). Verification and Validation testing and the Risk Management Report demonstrate that AutoContour Model RADAC V3 is as safe and effective as the Predicate Device. The technological characteristics table demonstrates the similarity between AutoContour Model RADAC V3 and the Predicate Device and does not raise any questions on the safety and effectiveness of the Subject Device.