



December 9, 2024

Radformation, Inc.
Jennifer Wampler
Regulatory Affairs Specialist
261 Madison Avenue
9th Floor
New York, New York 10016

Re: K242729

Trade/Device Name: AutoContour (Model RADAC V4)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: September 5, 2024
Received: September 10, 2024

Dear Jennifer Wampler:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

Submission Number (if known)

K242729

Device Name

AutoContour (Model RADAC V4)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Syssock
Company:	Radformation, Inc.
Address:	261 Madison Avenue, 9th Floor New York, NY 10016
Contact Person:	Alan Nelson Chief Technology Officer, Radformation
Phone:	518-888-5727
Fax:	-----
Email:	anelson@radformation.com
Date of Summary Preparation	09/05/2024

5.2. Device Information

Table 2 : Device Information	
Trade Name:	AutoContour Model RADAC V4
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 V4 (Subject Device) makes use of its prior submissions - AutoContour Model RADAC V3 (K230685) - as the Predicate Device.

5.4. Device Description

As with AutoContour Model RADAC V3, the AutoContour Model RADAC V4 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 that can be imported into a radiation therapy treatment planning system.

AutoContour Model RADAC V4 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 V4 makes use of AutoContour Model RADAC V3 (K230685) as the Predicate Device for substantial equivalence comparison. The functionality and technical components of this prior submission remain unchanged in AutoContour Model RADAC V4. This submission is intended to build on the technological characteristics of the 510(k) cleared AutoContour Model RADAC V3 pertaining to new structure models for both CT and MRI.

5.6.1. Updates vs. AutoContour (K230685)

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 V4 vs. AutoContour Model RADAC V3 (K230685)		
Characteristic	Subject Device: AutoContour Model RADAC V4	Predicate Device: AutoContour Model RADAC V3 (K230685)
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 and REGISTRATION for input. <i>(Minor differences)</i>	CT or MR input for contouring or registration/fusion. PET/CT input for registration/fusion only. DICOM RTSTRUCT and REGISTRATION for input.
Design: Reporting and data routing	No built-in reporting, supports exporting DICOM RTSTRUCT, REGISTRATION and DOSE files. <i>(Minor differences)</i>	No built-in reporting, supports exporting DICOM RTSTRUCT file. <i>(Substantially Equivalent)</i>

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_Brachiocephls • A_Carotid_L • A_Carotid_R • A_Coronary • A_LAD • A_Pulmonary • A_Subclavian_L • A_Subclavian_R • Atrium_L • Atrium_R • Bladder • Bladder_F • Bone_Hyoid • Bone_Ilium_L • Bone_Ilium_R • Bone_Mandible • Bone_Pelvic • Bone_Skull • Bone_Sternum • Bone_Teeth • Bowel • Bowel_Bag • Bowel_Large • Bowel_Small • BrachialPlex_L • BrachialPlex_R • Brain • Brainstem • Breast_L • Breast_R • Breast_Prone • Bronchus • BuccalMucosa • Carina • CaudaEquina • Cavity_Oral • Cavity_Oral_Ext • Chestwall_L • Chestwall_OAR • Chestwall_R • Chestwall_RC_L • Chestwall_RC_R • Clavicle_L	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
---------------------------------------	---	--

	• Clavicle_R • Cochlea_L • Cochlea_R • Colon_Sigmoid • Cornea_L • Cornea_R • Dental_Artifact • Duodenum • Ear_Internal_L • Ear_Internal_R • Esophagus • External • Eye_L • Eye_R • Femur_Head_L • Femur_Head_R • Femur_L • Femur_R • Femur_RTOG_L • Femur_RTOG_R • Foley_Balloon • GallBladder • Genitals_F • Genitals_M • GlnD_LacrimaL_L • GlnD_LacrimaL_R • GlnD_Submand_L • GlnD_Submand_R • GlnD_Thyroid • HDR_Bladder • HDR_Bowel • HDR_Cylinder • HDR_Rectum • Heart • Heart_Prone • Hippocampus_L • Hippocampus_R • Humerus_L • Humerus_R • Iliac_Int_L • Iliac_Int_R • Iliac_L • Iliac_R • Kidney_L • Kidney_R • Kidney_Outer_L • Kidney_Outer_R • Larynx • Larynx_Glottic • Larynx_NRG • Larynx_SG	• 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_L • Lens_R • Lips • Liver • LN_Ax_L • LN_Ax_L1_ESTRO_L • LN_Ax_L1_ESTRO_R • LN_Ax_L1_L • LN_Ax_L1_R • LN_Ax_L2_ESTRO_L • LN_Ax_L2_ESTRO_R • LN_Ax_L2_L • LN_Ax_L2_L3_L • LN_Ax_L2_L3_R • LN_Ax_L2_R • LN_Ax_L3_ESTRO_L • LN_Ax_L3_ESTRO_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_InPec_ESTRO_L • LN_InPec_ESTRO_R • LN_Neck_IA • LN_Neck_IB_L • LN_Neck_IB_R • 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_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_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
--	---	--

	• LN_Pelvics_F • LN_Pelvics • LN_Pelvic_NRG • LN_Post_Neck_L • LN_Post_Neck_R • LN_Presacral • LN_Sclav_ESTRO_L • LN_Sclav_ESTRO_R • 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 • Musc_Iliopsoas_L • Musc_Iliopsoas_R • Myocardium • Nipple_L • Nipple_Prone • Nipple_R • OpticChiasm • OpticNrv_L • OpticNrv_R • Pancreas • Parotid_L • Parotid_R • PenileBulb • Pericardium • Pharynx • Pituitary • Prostate • ProstateBed • Rectum • Rectum_F • Retina_L • Retina_R • Rib • Rib01_L • Rib01_R • Rib02_L • Rib02_R • Rib03_L • Rib03_R • Rib04_L	• 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 • GInd_Prostate • Hippocampus_L • Hippocampus_R • Hypo_True • Hypothalamus • OpticChiasm • OpticNrv_L • OpticNrv_R • OpticTract_L • OpticTract_R
--	---	--

	• Rib04_R • Rib05_L • Rib05_R • Rib06_L • Rib06_R • Rib07_L • Rib07_R • Rib08_L • Rib08_R • Rib09_L • Rib09_R • Rib10_L • Rib10_R • Rib11_L • Rib11_R • Rib12_L • Rib12_R • Rib_L • Rib_R • SacralPlex_L • SacralPlex_R • SeminalVes • SpinalCanal • SpinalCord • Spleen • Stomach • Trachea • UteroCervix • V_Brachioceph_L • V_Brachioceph_R • V_Jugular_L • V_Jugular_R • 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	• Pituitary • Prostate • SeminalVes
--	---	---

	• VB_T05 • VB_T06 • VB_T07 • VB_T08 • VB_T09 • VB_T10 • VB_T11 • VB_T12 • Ventricle_L • Ventricle_R MR Models: • A_Pud_Int_L • A_Pud_Int_R • Bladder • Bladder_Trigone • Brain • Brainstem • Cerebellum • Colon_Sigmoid • External_Pelvis • Eye_L • Eye_R • Femur_L • Femur_R • GlnD_Prostate • Hippocampus_L • Hippocampus_R • Hypo_True • Hypothalamus • Lens_L • Lens_R • NVB_L • NVB_R • OpticChiasm • OpticNrv_L • OpticNrv_R • OpticTract_L • OpticTract_R • PenileBulb • Pituitary • Prostate • Rectal_Spacer • Rectum • SeminalVes • SpinalCord_Cerv • Urethra	
Computer platform & Operating	Windows based .NET front-end application that also serves as agent Uploader supporting Microsoft Windows	Windows based .NET front-end application that also serves as agent Uploader

System	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.	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 V4 supports contouring **77** 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_Brachiocephls
- A_Carotid_L
- A_Carotid_R
- A_Coronary_R
- A_Subclavian_L
- A_Subclavian_R
- Atrium_L
- Atrium_R
- Bone_Hyoid

- Bone_Teeth
- Breast_Prone
- Clavicle_L
- Clavicle_R
- Dental_Artifact
- Foley_Balloon
- HDR_Bladder
- HDR_Bowel
- HDR_Rectum
- Heart_Prone
- Iliac_Int_L
- Iliac_Int_R
- Iliac_L
- Iliac_R
- LN_Ax_L1_ESTRO_L
- LN_Ax_L1_ESTRO_R
- LN_Ax_L2_ESTRO_L
- LN_Ax_L2_ESTRO_R
- LN_Ax_L3_ESTRO_L
- LN_Ax_L3_ESTRO_R
- LN_InPec_ESTRO_L
- LN_InPec_ESTRO_R
- LN_Neck_IB_L
- LN_Neck_IB_R
- LN_Pelvics_F
- LN_Post_Neck_L
- LN_Post_Neck_R
- LN_Presacral
- LN_Sclav_ESTRO_L

- LN_Sclav_ESTRO_R
- Musc_Iliopsoas_L
- Musc_Iliopsoas_R
- Myocardium
- Nipple_Prone
- Pharynx
- ProstateBed
- Rib_R
- Rib01_L
- Rib01_R
- Rib02_L
- Rib02_R
- Rib03_L
- Rib03_R
- Rib04_L
- Rib04_R
- Rib05_L
- Rib05_R
- Rib06_L
- Rib06_R
- Rib07_L
- Rib07_R
- Rib08_L
- Rib08_R
- Rib09_L
- Rib09_R
- Rib10_L
- Rib10_R
- Rib11_L

- Rib11_R
- Rib12_L
- Rib12_R
- SacralPlex_L
- SacralPlex_R
- V_Brachioceph_L
- V_Brachioceph_R
- V_Jugular_L
- V_Jugular_R
- Ventricle_L
- Ventricle_R
- **New MR Models:**

Compared with the Predicate Device, AutoContour Model RADAC V4 supports contouring **18** 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 MR 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_Pud_Int_L
 - A_Pud_Int_R
 - Bladder
 - Bladder_Trigone
 - Brain
 - Colon_Sigmoid
 - External_Pelvis
 - Femur_L
 - Femur_R
 - Lens_L
 - Lens_R

- NVB_L
- NVB_R
- PenileBulb
- Rectal_Spacer
- Rectum
- SpinalCord_Cerv
- Urethra
- New DICOM outputs

AutoContour Model RADAC 4 now supports the export of the Deformable Registration and Deformed Dose to DICOM such that these Registrations and Dose grids to be reviewed as needed in outside Treatment Planning Systems and be evaluated for accuracy within independent Registration QA Systems. This minor difference does not represent a decrease in safety or effectiveness relative to the Predicate Device because:

- The ability to generate Deformable Registrations and Dose files was previously supported within the predicate device (AutoContour RADAC V2 and V3) for the purposes of structure transfer and dose summation evaluation of previously treated plans in ClearCheck.
- The same risk mitigations present in the predicate device (i.e. registration approval and review tools) are present in the AutoContour RADAC 4.
- Users are provided with the option to validate the appropriateness of the AutoContour Deformable Registration algorithm within independent review platforms (eg. Treatment Planning system)

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 V4. Non-clinical tests were performed according to Radformation's AutoContour Complete Test Protocol and Report, which demonstrates that AutoContour Model RADAC V4 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.

Description of Changes to Test Protocol

There were no changes to the testing protocol between AutoContour RADAC V3 and RADAC V4.

Testing Summary

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 341 training and 54 testing image sets. CT training images were gathered from 4 institutions, in 2 different countries, the United States and Switzerland.

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 0.92 $\pm$ 0.06, 0.85 $\pm$ 0.09, and 0.81 $\pm$ 0.12 respectively. A full summary of the CT structure DSC is available below:

Table 4: CT Training Data Results for AutoContour Model RADAC V4							
CT Structure	Size	Pass Criteria	# of Training Sets	# of Testing Sets	DSC (Avg)	DSC Std Dev	Lower Bound 95% Confidence Interval

A_Brachiocephls	Small	0.50	388	97	0.88	0.16	0.6168
A_Carotid_L	Medium	0.65	328	83	0.79	0.13	0.57615
A_Carotid_R	Medium	0.65	328	83	0.79	0.13	0.57615
A_Coronary_R	Small	0.50	408	116	0.56	0.09	0.41195
A_Subclavian_L	Small	0.50	388	97	0.86	0.17	0.58035
A_Subclavian_R	Small	0.50	388	97	0.89	0.14	0.6597
Atrium_L	Medium	0.65	1082	65	0.92	0.1	0.7555
Atrium_R	Medium	0.65	1082	65	0.89	0.13	0.67615
Bone_Hyoid	Small	0.50	305	77	0.82	0.03	0.77065
Bone_Teeth	Medium	0.65	340	76	0.88	0.02	0.8471
Breast_Prone	Large	0.80	245	63	0.93	0.04	0.8642
Clavicle_L	Medium	0.65	1082	65	0.95	0.02	0.9171
Clavicle_R	Medium	0.65	1082	65	0.95	0.01	0.93355
Dental_Artifact	Medium	0.65	342	86	0.76	0.1	0.5955
Foley_Balloon	Small	0.50	36	10	0.78	0.16	0.5168
HDR_Bladder	Medium	0.65	383	96	0.93	0.08	0.7984
HDR_Bowel	Medium	0.65	56	15	0.77	0.26	0.3423
HDR_Rectum	Medium	0.65	131	33	0.86	0.04	0.7942
Heart_Prone	Large	0.80	308	78	0.97	0.01	0.95355
Iliac_Int_L	Medium	0.65	160	40	0.66	0.28	0.1994
Iliac_Int_R	Medium	0.65	160	40	0.66	0.28	0.1994
Iliac_L	Medium	0.65	1082	65	0.83	0.06	0.7313
Iliac_R	Medium	0.65	1082	65	0.81	0.08	0.6784
LN_Ax_L1_ESTRO_L	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Ax_L1_ESTRO_R	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Ax_L2_ESTRO_L	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Ax_L2_ESTRO_R	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Ax_L3_ESTRO_L	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Ax_L3_ESTRO_R	Medium	0.65	82	21	0.8	0.15	0.55325
LN_InPec_ESTRO_L	Medium	0.65	82	21	0.8	0.15	0.55325
LN_InPec_ESTRO_R	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Neck_IB_L	Medium	0.65	252	64	0.88	0.05	0.79775
LN_Neck_IB_R	Medium	0.65	252	64	0.88	0.05	0.79775
LN_Pelvics_F	Large	0.80	82	21	0.89	0.02	0.8571
LN_Post_Neck_L	Medium	0.65	240	60	0.83	0.05	0.74775

LN_Post_Neck_R	Medium	0.65	240	60	0.83	0.05	0.74775
LN_Presacral	Medium	0.65	191	48	0.78	0.16	0.5168
LN_Sclav_ESTRO_L	Medium	0.65	82	21	0.8	0.15	0.55325
LN_Sclav_ESTRO_R	Medium	0.65	82	21	0.8	0.15	0.55325
Musc_Iliopsoas_L	Large	0.80	1082	65	0.94	0.08	0.8084
Musc_Iliopsoas_R	Large	0.80	1082	65	0.94	0.14	0.7097
Myocardium	Medium	0.65	1082	65	0.9	0.05	0.81775
Nipple_Prone	Small	0.50	247	62	0.72	0.1	0.5555
Pharynx	Medium	0.65	57	15	0.9	0.02	0.8671
ProstateBed	Medium	0.65	133	34	0.87	0.04	0.8042
Rib01_L	Medium	0.65	148	37	0.74	0.3	0.2465
Rib01_R	Medium	0.65	148	37	0.89	0.07	0.77485
Rib02_L	Medium	0.65	148	37	0.9	0.06	0.8013
Rib02_R	Medium	0.65	148	37	0.9	0.06	0.8013
Rib03_L	Medium	0.65	148	37	0.9	0.07	0.78485
Rib03_R	Medium	0.65	148	37	0.89	0.07	0.77485
Rib04_L	Medium	0.65	148	37	0.87	0.16	0.6068
Rib04_R	Medium	0.65	148	37	0.91	0.07	0.79485
Rib05_L	Medium	0.65	148	37	0.9	0.07	0.78485
Rib05_R	Medium	0.65	148	37	0.88	0.1	0.7155
Rib06_L	Medium	0.65	148	37	0.92	0.06	0.8213
Rib06_R	Medium	0.65	148	37	0.92	0.06	0.8213
Rib07_L	Medium	0.65	148	37	0.92	0.06	0.8213
Rib07_R	Medium	0.65	148	37	0.92	0.07	0.80485
Rib08_L	Medium	0.65	148	37	0.91	0.06	0.8113
Rib08_R	Medium	0.65	148	37	0.89	0.17	0.61035
Rib09_L	Medium	0.65	148	37	0.92	0.05	0.83775
Rib09_R	Medium	0.65	148	37	0.91	0.06	0.8113
Rib10_L	Medium	0.65	148	37	0.91	0.06	0.8113
Rib10_R	Medium	0.65	148	37	0.91	0.06	0.8113
Rib11_L	Medium	0.65	148	37	0.9	0.06	0.8013
Rib11_R	Medium	0.65	148	37	0.9	0.08	0.7684
Rib12_L	Small	0.50	148	37	0.89	0.08	0.7584
Rib12_R	Small	0.50	148	37	0.9	0.07	0.78485
SacralPlex_L	Medium	0.65	326	83	0.75	0.06	0.6513

SacralPlex_R	Medium	0.65	326	83	0.75	0.06	0.6513
V_Brachioceph_L	Medium	0.65	388	97	0.91	0.1	0.7455
V_Brachioceph_R	Small	0.50	388	97	0.86	0.19	0.54745
V_Jugular_L	Medium	0.65	165	42	0.76	0.08	0.6284
V_Jugular_R	Medium	0.65	165	42	0.76	0.08	0.6284
Ventricle_L	Medium	0.65	1082	65	0.95	0.04	0.8842
Ventricle_R	Medium	0.65	1082	65	0.97	0.07	0.85485

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. 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 Elmp, 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
CT Thorax Prone Female	TCIA- QIN-BREAST and Prone Thorax	Li, X., Abramson, R. G., Arlinghaus, L. R., Chakravarthy, A. B., Abramson, V. G., Sanders, M., & Yankeelov, T. E. (2016). Data From QIN-BREAST (Version 2) [Data set]. The Cancer Imaging Archive.

		https://doi.org/10.7937/K9/TCIA.2016.21JUEBH0 N/A- Testing data was shared from several institutions
CT HDR Female	Female HDR Pelvis	N/A- Testing data was shared from 2 different institutions based in the United States.
CT Prostatectomy	Pelvis ProstateBed	N/A- Testing data was shared from 1 institution based in the United States

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 0.76+/-0.09, 0.84+/-0.09, and 0.94+/-0.02 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 4.57 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.

Table 6: CT External Reviewer Results for AutoContour Model RADAC V4							
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_Aorta (Update)	Large	0.8	39	0.95	0.03	0.89582266	4.6
A_Aorta_Asc (Update)	Medium	0.65	39	0.94	0.06	0.842291865	4.6
A_Brachiocephls	Small	0.5	40	0.83	0.09	0.68945428	4.6
A_Carotid_L	Medium	0.65	82	0.79	0.09	0.64324782	4.6
A_Carotid_R	Medium	0.65	82	0.77	0.12	0.563546295	4.55
A_LAD (Update)	Small	0.5	41	0.62	0.099	0.453008335	4.8
A_Coronary_R	Small	0.5	40	0.55	0.13	0.32397622	4.4
A_Subclavian_L	Small	0.5	40	0.86	0.05	0.76936995	4.7
A_Subclavian_R	Small	0.5	40	0.83	0.08	0.70220291	4.9

Atrium_L	Medium	0.65	20	0.96	0.01	0.93505483	5
Atrium_R	Medium	0.65	20	0.95	0.02	0.92325817	4.3
Bone_Hyoid	Small	0.5	23	0.80	0.04	0.728027755	4.3
Bone_Teeth	Medium	0.65	22	0.85	0.03	0.801330455	4.3
Breast_Prone	Large	0.8	20	0.93	0.02	0.89735428	4.4
Clavicle_L	Medium	0.65	40	0.92	0.02	0.88753772	4.5
Clavicle_R	Medium	0.65	40	0.92	0.01	0.8942826	4.5
Dental_Artifact	Medium	0.65	20	0.65	0.17	0.375672405	4.3
Esophagus (update)	Medium	0.65	62	0.85	0.04	0.777605135	4.7
Foley_Balloon	Small	0.5	13	0.91	0.06	0.82063068	4.7
Gallbladder (Update)	Medium	0.65	22	0.87	0.05	0.785888125	4.8
HDR_Bladder	Medium	0.65	21	0.91	0.13	0.698258845	4.8
HDR_Bowel	Medium	0.65	21	0.93	0.04	0.863923615	4.4
HDR_Rectum	Medium	0.65	21	0.90	0.05	0.81869892	4.6
Heart_Prone	Large	0.8	21	0.95	0.02	0.90959547	4.9
Iliac_Int_L	Medium	0.65	41	0.80	0.06	0.699809155	4.75
Iliac_Int_R	Medium	0.65	41	0.80	0.09	0.651761885	4.7
Iliac_L	Medium	0.65	41	0.89	0.07	0.7751705	4.5
Iliac_R	Medium	0.65	41	0.85	0.08	0.726148045	4.45
Liver (update)	Large	0.8	36	0.97	0.01	0.955394055	4.9
LN_Ax_L1_ESTRO_L	Medium	0.65	37	0.91	0.06	0.80772404	4.5
LN_Ax_L1_ESTRO_R	Medium	0.65	34	0.90	0.06	0.79726031	4.5
LN_Ax_L2_ESTRO_L	Medium	0.65	37	0.94	0.05	0.853433065	4.5
LN_Ax_L2_ESTRO_R	Medium	0.65	34	0.93	0.04	0.86185477	4.5
LN_Ax_L3_ESTRO_L	Medium	0.65	37	0.94	0.05	0.84602869	4.3
LN_Ax_L3_ESTRO_R	Medium	0.65	34	0.92	0.05	0.848240015	4.3

R							
LN_InPec_ESTRO_L	Medium	0.65	37	0.90	0.06	0.791700585	4.5
LN_InPec_ESTRO_R	Medium	0.65	34	0.90	0.06	0.798294905	4.5
LN_Neck_IB_L	Medium	0.65	23	0.85	0.03	0.80514656	4.1
LN_Neck_IB_R	Medium	0.65	23	0.86	0.02	0.81966185	4.1
LN_Pelvics_F	Large	0.8	20	0.82	0.04	0.759259815	3.8
LN_Post_Neck_L	Medium	0.65	20	0.81	0.11	0.625135715	4.1
LN_Post_Neck_R	Medium	0.65	20	0.80	0.11	0.627514085	4
LN_Presacral	Medium	0.65	40	0.82	0.07	0.695967485	4.45
LN_Sclav_ESTRO_L	Medium	0.65	37	0.88	0.07	0.75887216	4.5
LN_Sclav_ESTRO_R	Medium	0.65	34	0.86	0.07	0.73523028	4.5
Lung_L (Update)	Large	0.8	48	0.98	0.01	0.97306078	4.95
Lung_R (Update)	Large	0.8	48	0.99	0.01	0.980571135	4.9
Musc_Iliopsoas_L	Large	0.8	41	0.92	0.03	0.88255485	4.7
Musc_Iliopsoas_R	Large	0.8	41	0.92	0.02	0.879852935	4.65
Myocardium	Medium	0.65	20	0.98	0.01	0.96066337	4.7
Nipple_Prone	Small	0.5	20	0.57	0.18	0.28356733	4.8
Pharynx	Medium	0.65	23	0.83	0.04	0.76067133	4.6
ProstateBed	Medium	0.65	20	0.90	0.06	0.802275555	4.4
Rib01_L	Medium	0.65	40	0.81	0.09	0.66151844	4.6
Rib01_R	Medium	0.65	40	0.81	0.11	0.633076305	4.7
Rib02_L	Medium	0.65	40	0.83	0.09	0.685388515	4.7
Rib02_R	Medium	0.65	39	0.83	0.11	0.64919281	4.5
Rib03_L	Medium	0.65	40	0.83	0.12	0.62952629	4.5
Rib03_R	Medium	0.65	39	0.84	0.14	0.606939835	4.7
Rib04_L	Medium	0.65	38	0.85	0.07	0.73693755	4.7
Rib04_R	Medium	0.65	38	0.83	0.12	0.623241235	4.7

Rib05_L	Medium	0.65	37	0.85	0.14	0.610838085	4.5
Rib05_R	Medium	0.65	33	0.88	0.02	0.83649353	4.6
Rib06_L	Medium	0.65	40	0.86	0.08	0.724382375	4.5
Rib06_R	Medium	0.65	40	0.86	0.12	0.662757125	4.6
Rib07_L	Medium	0.65	40	0.85	0.14	0.625797495	4.6
Rib07_R	Medium	0.65	40	0.86	0.14	0.624501425	4.7
Rib08_L	Medium	0.65	40	0.85	0.14	0.62039746	4.5
Rib08_R	Medium	0.65	40	0.85	0.14	0.619059365	4.6
Rib09_L	Medium	0.65	40	0.84	0.14	0.608365215	4.7
Rib09_R	Medium	0.65	40	0.82	0.20	0.496094935	4.5
Rib10_L	Medium	0.65	40	0.82	0.19	0.505475645	4.7
Rib10_R	Medium	0.65	40	0.795	0.23	0.41650505	4.8
Rib11_L	Medium	0.65	39	0.79	0.19	0.473883335	4.8
Rib11_R	Medium	0.65	39	0.79	0.23	0.405756435	4.7
Rib12_L	Small	0.5	29	0.77	0.14	0.539397945	4.7
Rib12_R	Small	0.5	28	0.81	0.10	0.6521935	4.9
SacralPlex_L	Medium	0.65	61	0.71	0.07	0.59617898	4.75
SacralPlex_R	Medium	0.65	41	0.73	0.05	0.6399795	4.75
V_Brachioceph_L	Medium	0.65	40	0.81	0.15	0.56550252	4.8
V_Brachioceph_R	Small	0.5	40	0.86	0.06	0.754842185	4.7
V_Jugular_L	Medium	0.65	82	0.77	0.12	0.565053955	4.35
V_Jugular_R	Medium	0.65	82	0.78	0.20	0.62129336	4.35
V_Venacava_S (Update)	Medium	0.65	39	0.91	0.04	0.84602356	4.4
Ventricle_L	Medium	0.65	20	0.99	0.004	0.98438629	4.6
Ventricle_R	Medium	0.65	20	0.97	0.01	0.953399715	4.7

The MR training data set used for initial testing of the Brain models (SpinalCord_Cerv, Brain, and Lens_L/R) had an average of 149 training image sets and 45 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 (A_Pud_Int_L/R, Bladder, Bladder_Trigone, Colon_Sigmoid, External_Pelvis, Femur_L/R, NVB_L/R, PenileBulb, Rectal_Spacer, Rectum, and Urethra) had an average of 306 training image sets and 77 testing image sets and were taken from 2 open source datasets, and one institution within the United States.

Table 7: MR Initial Testing Dataset References		
Model Group	Data Source ID	Data Citation
MR Brain	MR - Renown	Shusharina, N., & Bortfeld, T. (2021). <i>Glioma Image Segmentation for Radiotherapy: RT targets, barriers to cancer spread, and organs at risk</i> [Data set]. The Cancer Imaging Archive. https://doi.org/10.7937/TCIA.T905-ZQ20
MR Pelvis	Prostate-MRI-US-Biopsy	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
MR Pelvis_2	NYP	N/A- Testing data was shared by 1 institution
MR Pelvis_3	ProstateX	Litjens, G., Debats, O., Barentsz, J., Karssemeijer, N., & Huisman, H. (2017). SPIE-AAPM PROSTATEx Challenge Data (Version 2) [dataset]. The Cancer Imaging Archive. https://doi.org/10.7937/K9TCIA.2017.MURS5CL

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 0.96+/-0.03 was found for large models, 0.84+/-0.07 for medium models, 0.74+/- 0.09 for small models.

Table 8: MR Training Data Results for AutoContour Model RADAC V4					
MR Models	Size	Pass Criteria	DSC (Avg)	DSC Std Dev (Avg)	Lower Bound 95% Confidence Interval
A_Pud_Int_L	Small	0.5	0.69	0.08	0.5584

A_Pud_Int_R	Small	0.5	0.69	0.08	0.5584
Bladder	Large	0.8	0.92	0.07	0.80485
Bladder_Trigone	Small	0.5	0.72	0.05	0.63775
Brain	Large	0.8	0.97	0	0.97
Colon_Sigmoid	Medium	0.65	0.72	0.18	0.4239
External_Pelvis	Large	0.8	0.99	0.01	0.97355
Femur_L	Medium	0.65	0.93	0.03	0.88065
Femur_R	Medium	0.65	0.93	0.03	0.88065
Lens_L	Small	0.5	0.82	0.09	0.67195
Lens_R	Small	0.5	0.82	0.09	0.67195
NVB_L	Small	0.5	0.61	0.08	0.4784
NVB_R	Small	0.5	0.61	0.08	0.4784
PenileBulb	Small	0.5	0.79	0.12	0.5926
Rectal_Spacer	Medium	0.65	0.84	0.12	0.6426
Rectum	Medium	0.65	0.88	0.1	0.7155
SpinalCord_Cerv	Small	0.5	0.82	0.06	0.7213
Urethra	Medium	0.65	0.68	0.09	0.53195

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." <i>Medical Physics</i> 12 (10): 3218–21. doi:10.1002/mp.12748.
MR Pelvis_2	SynthRad	Thummerer A, van der Bijl E, Galapon Jr A, Verhoeff JJ, Langendijk JA, Both S, van den Berg CAT, Maspero M. 2023. SynthRAD2023 Grand Challenge dataset: Generating synthetic CT for radiotherapy. <i>Medical Physics</i> , 50(7), 4664-4674. https://doi.org/10.1002/mp.16529
MRLinac Pelvis	MR Linac	N/A- Testing data was shared by 2 institutions utilizing MR Linacs for image acquisitions.

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 2 publicly available datasets, which contained images of patients with prostate or rectal cancer, as well as 1 dataset shared from 2 institutions utilizing an MR Linac. Various scanner models and acquisition settings were used.

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, medium, and large structures with a mean DSC of 0.61+/-0.14, 0.84+/-0.09, 0.80+/-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 4.6 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 V4

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)
A_Pud_Int_L	Small	0.5	45	0.57	0.11	0.39913191	4.9
A_Pud_Int_R	Small	0.5	45	0.58	0.10	0.47111123	4.9
Bladder	Large	0.8	45	0.93	0.06	0.824646915	4.8
Bladder_Trigone	Medium	0.5	45	0.59	0.13	0.379483905	4.6
Brain	Large	0.8	20	0.97	0.01	0.959101725	4.6
Colon_Sigmoid	Medium	0.65	45	0.74	0.21	0.406063225	4.5
External_Pelvis	Large	0.8	6	0.99	0.001	0.98960849	5
Femur_L	Medium	0.65	44	0.94	0.02	0.90950333	4.6
Femur_R	Medium	0.65	45	0.95	0.01	0.921129565	4.5
GlnD_Prostate (Update)	Medium	0.65	45	0.83	0.07	0.71662536	4.8
Lens_L	Small	0.5	18	0.72	0.14	0.487633895	4.6
Lens_R	Small	0.5	19	0.63	0.21	0.268851055	4.6
NVB_L	Small	0.5	45	0.54	0.12	0.34080495	4.2
NVB_R	Small	0.5	45	0.50	0.12	0.305008105	4.2

PenileBulb	Small	0.5	45	0.71	0.18	0.40456992	4.8
Prostate(Update)	Medium	0.65	45	0.86	0.04	0.7887511	4.8
Rectal_Spacer	Small	0.5	5	0.51	.22	0.1481	3.9
Rectum	Medium	0.65	45	0.84	0.07	0.721510645	4.5
SeminalVes (Update)	Medium	0.65	45	0.69	0.16	0.43922276	4.6
SpinalCord_Cerv	Small	0.5	18	0.837	0.08	0.704194545	4.6
Urethra	Small	0.5	26	0.56	0.13	0.35090269	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 V4 is deemed substantially equivalent to the Predicate Device, AutoContour Model RADAC V3 (K220598). Verification and Validation testing and the Risk Management Report demonstrate that AutoContour Model RADAC V4 is as safe and effective as the Predicate Device. The technological characteristics table demonstrates the similarity between AutoContour Model RADAC V4 and the Predicate Device and does not raise any questions on the safety and effectiveness of the Subject Device.