MIM Software Inc.
% Lynn Hanigan
Principal Regulatory and Quality Specialist
25800 Science Park Drive, Suite 180
CLEVELAND, OH 44122

November 8, 2023

Re: K231765
Trade/Device Name: Contour ProtégéAI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QKB
Dated: October 9, 2023
Received: October 10, 2023

Dear Lynn Hanigan:

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.

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

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

Sincerely,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K231765

Device Name
Contour ProtégéAI

Indications for Use *(Describe)*
Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications:

• Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

• Segmenting anatomical structures across a variety of CT anatomic locations.

• And segmenting the prostate, the seminal vesicles, and the urethra within T2-weighted MR images.

Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.

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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Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

510(k) Summary of Safety and Effectiveness
(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25800 Science Park Drive – Suite 180
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: October 5, 2023

Device Name

Trade Name:	Contour ProtégéAI
Common Name:	Medical Imaging Software
Regulation Number / Product Code:	21 CFR 892.2050 Product Code QKB
Classification Name:	Radiological Image Processing Software For Radiation Therapy

Predicate Devices

Primary -	K223774	Contour ProtégéAI	MIM Software Inc.
Reference -	K071964	MIM 4.1 SEASTAR (tradename MIM Maestro)	MIMvista Corp.

Intended Use

Contour ProtégéAI is an accessory to MIM software. It includes processing components to automatically contour imaging data using machine-learning based algorithms.

Contour ProtégéAI must be used in conjunction with MIM software to review and, if necessary, edit results automatically generated by Contour ProtégéAI.

Contour ProtégéAI is not intended to automatically detect lesions.

Indications for Use

Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications:

- Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation

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therapy treatment planning systems, and archiving contours for patient follow-up and management.

- Segmenting anatomical structures across a variety of CT anatomical locations.
- And segmenting the prostate, the seminal vesicles, and the urethra within T2-weighted MR images.

Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.

Device Description

Contour ProtégéAI is an accessory to MIM software that automatically creates contours on medical images through the use of machine-learning algorithms. It is designed for use in the processing of medical images and operates on Windows, Mac, and Linux computer systems. Contour ProtégéAI is deployed on a remote server using the MIMcloud service for data management and transfer; or locally on the workstation or server running MIM software.

A total of 550 CT images from 41 clinical sites across multiple continents was gathered for the training of the final 4.1.0 neural network models. The following table lists the data used for the training of the 4.1.0 final production models. Across the training data, 56.4% were male, 25.8% were female, and 17.8% were not labeled. Training data patient age ranges were 1-20: 0.2%, 20-40: 1.8%, 40-60: 8.9%, 60+: 24.2%, and not labeled 64.9%. Images were acquired by scanners made by: Phillips, 38.5%, GE, 17.6%; Siemens, 16.2%; Toshiba, 2.7% and not labeled 25.0%. Over the dataset, 38.7% of the images were acquired with IV or oral contrast, and 61.3% were acquired with no contrast.

Table1: CT data used to train the final production of the 4.1.0 CT models.

Institution	Country	# of images
Institution 1	USA	2
Institution 2	USA	5
Institution 3	USA	26
Institution 4	USA	8
Institution 5	USA	3
Institution 6	USA	1
Institution 7	USA	34
Institution 8	USA	17
Institution 9	USA	6
Institution 10	Hong Kong	30
Institution 11	USA	13
Institution 12	USA	6
Institution 13	USA	10
Institution 14	USA	6
Institution 15	USA	24
Institution 16	USA	2
Institution 17	USA	14

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Institution	Country	# of images
Institution 18	USA	7
Institution 19	USA	27
Institution 20	USA	27
Institution 21	USA	6
Institution 22	USA	41
Institution 23	Australia	19
Institution 24	USA	10
Institution 25	USA	11
Institution 26	USA	10
Institution 27	USA	2
Institution 28	USA	1
Institution 29	USA	6
Institution 30	USA	9
Institution 31	USA	4
Institution 32	USA	2
Institution 33	USA	6
Institution 34	USA	2
Institution 35	USA	6
Institution 36	USA	14
Institution 37	USA	4
Institution 38	USA	5
Institution 39	USA	75
Institution 40	Australia	48
Institution 41	USA	1

Substantial Equivalence

ITEM	Subject Device: Contour ProtégéAI (K231765)	Predicate Device: Contour ProtégéAI (K223774)	Reference Predicate: MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Clearance Dates	TBD	04/06/2023	9/26/2007

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ITEM	Subject Device: Contour ProtégéAI (K231765)	Predicate Device: Contour ProtégéAI (K223774)	Reference Predicate: MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Intended Use	Contour ProtégéAI is an accessory to MIM software used for the contouring of anatomical structures in imaging data using machine-learning-based algorithms automatically. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI. Contour ProtégéAI is not intended to detect or contour lesions.	Contour ProtégéAI is an accessory to MIM software used for the contouring of anatomical structures in imaging data using machine-learning-based algorithms automatically. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI. Contour ProtégéAI is not intended to detect or contour lesions.	MIM 4.1 (SEASTAR) software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists. MIM 4.1 (SEASTAR) is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, print and process digital medical images, as well as create, display and print reports from those images. The medical modalities of these medical imaging systems include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) provides tools to quickly create, transform, and modify contours for

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ITEM	Subject Device: Contour ProtégéAI (K231765)	Predicate Device: Contour ProtégéAI (K223774)	Reference Predicate: MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
			applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems and archiving contours for patient follow-up and management.
Indications for Use	Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications: • Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management. • Segmenting anatomical structures across a variety of CT anatomical locations. • And segmenting the prostate, the seminal vesicles, and the urethra	Trained medical professionals use Contour ProtégéAI as a tool to assist in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. In addition, Contour ProtégéAI supports the following indications: • Creation of contours using machine-learning algorithms for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management. • Segmenting anatomical structures across a variety of CT anatomical locations. • And segmenting the prostate, the seminal vesicles, and the urethra	MIM 4.1 (SEASTAR) software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) assists in the following indications: • Receive, transmit, store, retrieve, display, print, and process medical images

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	within T2-weighted MR images. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.	within T2-weighted MR images. Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.	and DICOM objects. • Create, display and print reports from medical images. • Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning. • Localization and definition of objects such as tumors and normal tissues in medical images. • Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

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Modalities	CT and MR	CT and MR	CT, MR, CR, DX, MG, US, SPECT, PET and XA
Atlas-Based Segmentation	No	No	Yes
Automatically Contour Imaging Data Using Machine-Learning	Yes	Yes	No
Operating Platform	Server-based application supporting Linux-based OS - and - Local deployment on Windows or Mac	Server-based application supporting Linux-based OS - and - Local deployment on Windows or Mac	Windows, Mac
Cloud-based deployment	Yes	Yes	No
Locally deployed (or installed)	Yes	Yes	No

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Neural Network Models included	***(1.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Liver CT Prostate MR ***(1.1.0 model)*** Prostate MR ***(2.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Abdomen CT Lungs and Liver CT ***(3.1.0 models)**** Head and Neck CT Prostate CT Thorax CT Abdomen CT Lungs and Liver CT MRT Additional Structures CT **(4.0.0 models)** Head and Neck CT Thorax CT Abdomen CT Pelvis CT	***(1.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Liver CT Prostate MR ***(1.1.0 model)*** Prostate MR ***(2.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Abdomen CT Lungs and Liver CT ***(3.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Abdomen CT Lungs and Liver CT MRT Additional Structures CT **(4.0.0 models)** Head and Neck CT Thorax CT Abdomen CT Pelvis CT	None

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ITEM	Subject Device: Contour ProtégéAI (K231765)	Predicate Device: Contour ProtégéAI (K223774)	Reference Predicate: MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	SurePlan MRT CT **(4.1.0 models)** Head and Neck CT Thorax CT Whole Body – Physiological Uptake Organs CT	SurePlan MRT CT	

Discussion

Changes within this submission include new 4.1.0 neural network models with additional contours. These changes differ when comparing to Contour ProtégéAI 510(K)223774. Non-inferiority testing was used to compare the proposed Contour ProtégéAI device to Atlases created from the MIM Maestro (K071964) reference device.

Testing and Performance Data

The proposed Contour ProtégéAI device were then evaluated on the test subjects from a pool of 754 independent images gathered from 27 institutions.

The CT images for this training set were obtained from clinical treatment plans for patients prescribed external beam or molecular radiotherapy, but the original segmentations were not used. Instead, the images were re-segmented by consultants (physicians and dosimetrists) specifically for this purpose, outside of clinical practice. Detailed instructions derived from relevant published clinical contouring guidelines were prepared for the dosimetrists. The initial segmentations were then reviewed and corrected by a radiation oncologist against the same standards and guidelines. Qualified staff at MIM Software (M.D. or licensed dosimetrists) then performed a final review and correction. All segmenters and reviewers were instructed to spend additional time to ensure the highest quality training data. In particular, the consultants were asked to contour all specified OAR structures on all images according to referenced standards, whether or not they were proximal to the treatment field. All patients were imaged on an indexed couch in treatment position (“simulation CT”). Series that were non-axial, had slices thinner than 0.5mm, or had non-Fan Beam or MV acquisitions were excluded.

The verification data used for testing is from a set of institutions that are totally disjoint from the training datasets used to train each model in the Contour ProtégéAI device. The reference predicate MIM device was configured with Atlases built from the same training data used to train

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the models. We tested Contour ProtégéAI against the reference predicate device, and the goal of this testing is to show that it is equivalent or superior to the reference predicate. The performance of both segmentation devices was measured by calculating both the Dice score and MDA of the novel segmentations with the original ground-truth contours. User beta testing was also used to evaluate the performance of Contour ProtégéAI in the context of time savings compared to contouring from scratch. This user evaluation was made on a three-point scale for each contour, with one indicating negligible time savings, two indicating moderate, and three indicating significant time savings. Our acceptance criteria combine the statistical tests and the user evaluation - only structures that pass two or more of the following three tests could be included in the final models:

- Statistical non-inferiority of the Dice score compared with the reference predicate.
- Statistical non-inferiority of the MDA score compared with the reference predicate.
- Average user evaluation of 2 or higher, when measured on a three-point scale.

Further clinical validation was also conducted in-house to evaluate contours compared to detailed criteria based on established clinical guidelines.

In addition, each model as a whole was also evaluated. In order to be included in the released product, the cumulative Added Path Length of the contours in the model was evaluated relative to the ground-truth. Cumulative APL has been found to correlate well with the total time spent in editing and correcting auto-segmented contours (Vaassen et al, 2020)[1]. Each model was required to have statistically non-inferior cumulative APL compared to the reference predicate.

Finally, the localization accuracy of each structure in all models was measured. We did not impose a passing criterion on localization accuracy; the results however are included in this summary document and in our User Guide and Whitepaper to allow the user to better understand the performance of the device.

Across the testing data the images 48.4% were female, 35.2% were male, and 16.4% were unknown for sex. The manufacturer was GE for 37.9% of images, 25.1% was Siemens, 15.0% were Philips, 0.4% were from Toshiba, and the other 21.6% were unknown. 4.38% were between the ages of 20-40, 21.5% were between 40-60, and 47.9% were over the age of 60. 26.0% were unknown, and 0.3% were under the age 20.

The mean and standard deviation Dice coefficients and MDA scores, along with the lower 95th percentile confidence bound, were calculated for both the proposed Contour ProtégéAI device and the MIM Maestro atlas segmentation reference device for each structure of each neural network model. Contour ProtégéAI results were equivalent or had better performance than the MIM Maestro atlas segmentation reference device. Equivalence is defined such that the lower 95th percentile confidence bound of the Contour ProtégéAI segmentation is greater than 0.1 Dice lower than the mean MIM atlas segmentation reference device performance.

Results over the validation set compared to the reference device are presented here:

Table 2: DICE, MDA and External Evaluation Score Comparison Per Structure

4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
Head and Neck	Bone_Mandible	0.81 ± 0.07	0.86 ± 0.07 (0.83) *	1.00 ± 0.87	0.64 ± 0.31 (0.93) *	2.86
	BrachialPlex_L	0.17 ± 0.08	0.22 ± 0.10 (0.14) *	3.24 ± 2.62	2.82 ± 2.61 (5.12) *	2.6

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4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	BrachialPlex_R	0.15 ± 0.07	0.19 ± 0.09 (0.11) *	3.62 ± 2.79	2.73 ± 2.38 (5.20) *	2.6
	Brain	0.97 ± 0.01	0.98 ± 0.01 (0.97) *	0.64 ± 0.37	0.52 ± 0.36 (0.66) *	2.71
	Brainstem	0.78 ± 0.09	0.82 ± 0.08 (0.78) *	1.72 ± 0.81	1.20 ± 0.65 (1.47) *	2.71
	Cavity_Oral	0.75 ± 0.14	0.76 ± 0.13 (0.68) *	3.34 ± 2.13	3.20 ± 1.93 (4.35) *	2.71
	Cochlea_L	0.19 ± 0.15	0.30 ± 0.18 (0.22) *	1.26 ± 0.85	1.17 ± 0.87 (1.58) *	2.29
	Cochlea_R	0.17 ± 0.15	0.32 ± 0.20 (0.23) *	1.12 ± 0.61	1.05 ± 0.68 (1.37) *	2.29
	Eye_L	0.80 ± 0.08	0.87 ± 0.06 (0.83) *	1.07 ± 0.60	0.65 ± 0.51 (0.91) *	2.57
	Eye_R	0.80 ± 0.10	0.86 ± 0.07 (0.82) *	1.11 ± 0.64	0.66 ± 0.48 (0.92) *	2.57
	Glnd_Lacrimal_L	0.22 ± 0.17	0.40 ± 0.16 (0.27) *	0.86 ± 0.54	0.68 ± 0.35 (1.05) *	2.71
	Glnd_Lacrimal_R	0.23 ± 0.16	0.45 ± 0.14 (0.34) *	0.73 ± 0.38	0.71 ± 0.52 (1.09) *	2.71
	Glnd_Submand_L	0.57 ± 0.13	0.77 ± 0.11 (0.69) *	1.74 ± 0.72	0.76 ± 0.32 (1.12) *	3
	Glnd_Submand_R	0.56 ± 0.16	0.75 ± 0.11 (0.65) *	1.82 ± 0.87	0.81 ± 0.34 (1.28) *	3
	Glnd_Thyroid	0.47 ± 0.18	0.71 ± 0.19 (0.57) *	2.55 ± 2.14	1.38 ± 3.18 (3.38) *	2.71
	Lens_L	0.22 ± 0.23	0.61 ± 0.17 (0.52) *	0.77 ± 0.54	0.56 ± 0.47 (0.84) *	2.29
	Lens_R	0.22 ± 0.22	0.63 ± 0.16 (0.54) *	0.81 ± 0.47	0.55 ± 0.33 (0.78) *	2.29
	Lips	0.38 ± 0.14	0.37 ± 0.15 (0.28) *	4.14 ± 2.86	5.26 ± 3.41 (7.27)	2.83
	OpticChiasm	0.04 ± 0.07	0.13 ± 0.13 (0.08) *	2.69 ± 1.87	2.46 ± 1.99 (3.55) *	2
	OpticNrv_L	0.45 ± 0.15	0.53 ± 0.14 (0.45) *	0.97 ± 0.81	0.77 ± 0.85 (1.19) *	2.57
	OpticNrv_R	0.44 ± 0.14	0.52 ± 0.13 (0.44) *	1.11 ± 1.24	0.80 ± 0.83 (1.34) *	2.57
	Parotid_L	0.71 ± 0.10	0.79 ± 0.09 (0.75) *	2.02 ± 0.95	1.30 ± 0.62 (1.68) *	3
	Parotid_R	0.71 ± 0.09	0.80 ± 0.06 (0.76) *	2.11 ± 0.76	1.26 ± 0.43 (1.56) *	3
	Pituitary	0.38 ± 0.18	0.54 ± 0.15	1.07 ± 0.59	0.87 ± 0.54	3

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4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
			(0.41) *		(1.29) *	
	SpinalCord	0.66 ± 0.14	0.65 ± 0.16 (0.59) *	0.81 ± 0.33	0.73 ± 0.41 (0.88) *	2.86
	LN_Neck_IA	0.48 ± 0.13	0.60 ± 0.14 (0.44) *	1.05 ± 1.51	0.47 ± 0.45 (1.81) *	2.75
	LN_Neck_IB_L	0.70 ± 0.05	0.79 ± 0.04 (0.73) *	1.30 ± 0.47	0.73 ± 0.24 (1.16) *	2.75
	LN_Neck_IB_R	0.68 ± 0.06	0.79 ± 0.05 (0.72) *	1.41 ± 0.51	0.73 ± 0.20 (1.19) *	2.75
	LN_Neck_IIA_L	0.64 ± 0.04	0.75 ± 0.05 (0.70) *	2.02 ± 0.54	1.54 ± 0.44 (2.09) *	2.25
	LN_Neck_IIA_R	0.60 ± 0.08	0.76 ± 0.04 (0.69) *	2.24 ± 0.76	1.41 ± 0.49 (2.15) *	2.25
	LN_Neck_IIB_L	0.68 ± 0.11	0.80 ± 0.06 (0.68) *	0.95 ± 0.49	0.63 ± 0.31 (1.12) *	3
	LN_Neck_IIB_R	0.68 ± 0.09	0.80 ± 0.06 (0.70) *	1.19 ± 0.64	0.58 ± 0.15 (1.14) *	3
	LN_Neck_III_L	0.54 ± 0.12	0.75 ± 0.07 (0.63) *	1.53 ± 0.60	0.92 ± 0.44 (1.51) *	3
	LN_Neck_III_R	0.57 ± 0.12	0.75 ± 0.07 (0.63) *	1.57 ± 0.61	0.99 ± 0.37 (1.57) *	3
	LN_Neck_IV_L	0.58 ± 0.08	0.69 ± 0.08 (0.59) *	1.62 ± 0.47	1.13 ± 0.37 (1.63) *	2.75
	LN_Neck_IV_R	0.55 ± 0.11	0.71 ± 0.09 (0.58) *	1.87 ± 0.75	1.06 ± 0.33 (1.77) *	2.75
	LN_Neck_V_L	0.53 ± 0.11	0.58 ± 0.09 (0.45) *	1.43 ± 0.82	1.13 ± 0.59 (2.02) *	3
	LN_Neck_V_R	0.50 ± 0.10	0.58 ± 0.11 (0.44) *	2.03 ± 1.66	1.43 ± 0.98 (3.18) *	3
	LN_Neck_VIA	0.34 ± 0.09	0.36 ± 0.11 (0.24) *	1.20 ± 0.55	0.80 ± 0.35 (1.33) *	2.75
	LN_Retropharynx_L	0.22 ± 0.07	0.28 ± 0.10 (0.19) *	1.44 ± 0.87	1.54 ± 1.47 (2.93) *	2.75
	LN_Retropharynx_R	0.21 ± 0.07	0.28 ± 0.09 (0.18) *	1.64 ± 0.93	1.49 ± 1.36 (2.82) *	2.75
	LN_Retrostyloid_L	0.57 ± 0.10	0.64 ± 0.09 (0.53) *	1.58 ± 0.75	1.23 ± 0.48 (1.96) *	2.75
	LN_Retrostyloid_R	0.56 ± 0.11	0.66 ± 0.11 (0.53) *	1.59 ± 0.74	1.13 ± 0.66 (1.95) *	2.75
Thorax	BrachialPlex_L	0.28 ± 0.14	0.38 ± 0.14 (0.26) *	2.96 ± 1.79	2.94 ± 1.84 (4.49) *	3
	BrachialPlex_R	0.28 ± 0.11	0.37 ± 0.16 (0.24) *	3.37 ± 2.27	3.28 ± 2.60 (5.51)	3

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4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	Breast_L	0.74 ± 0.11	0.76 ± 0.15 (0.66) *	4.86 ± 3.45	3.64 ± 1.85 (5.65) *	2.8
	Breast_R	0.76 ± 0.12	0.78 ± 0.15 (0.67) *	4.02 ± 1.70	3.45 ± 1.51 (4.66) *	2.6
	Bronchus	0.60 ± 0.17	0.66 ± 0.13 (0.55) *	2.18 ± 1.45	1.90 ± 1.22 (2.78) *	2.6
	Carina	0.36 ± 0.18	0.49 ± 0.12 (0.40) *	1.27 ± 0.55	1.03 ± 0.47 (1.33) *	2.4
	Cricoid	0.02 ± 0.04	0.04 ± 0.05 (-0.01) *	4.64 ± 1.54	5.71 ± 1.24 (7.05)	2.4
	Esophagus	0.48 ± 0.16	0.70 ± 0.15 (0.64) *	2.49 ± 2.48	0.97 ± 0.54 (1.56) *	2.8
	Glnd_Thyroid	0.46 ± 0.18	0.65 ± 0.17 (0.54) *	2.92 ± 2.60	1.75 ± 1.78 (3.19) *	2.75
	GreatVes	0.70 ± 0.08	0.74 ± 0.10 (0.65) *	3.37 ± 1.42	2.67 ± 1.73 (4.14) *	3
	Heart	0.88 ± 0.08	0.90 ± 0.09 (0.87) *	3.39 ± 1.91	2.55 ± 1.40 (3.06) *	3
	Humerus_Head_L	0.95 ± 0.02	0.95 ± 0.02 (0.94) *†	0.40 ± 0.23	0.40 ± 0.31 (0.63) *	2.8
	Humerus_Head_R	0.93 ± 0.09	0.96 ± 0.02 (0.90) *†	0.82 ± 2.37	0.31 ± 0.26 (1.81) *	2.8
	Kidney_L	0.74 ± 0.18	0.92 ± 0.05 (0.85) *	4.25 ± 3.38	0.94 ± 0.80 (2.27) *	3
	Kidney_R	0.74 ± 0.18	0.91 ± 0.07 (0.84) *	3.77 ± 2.28	0.98 ± 0.66 (1.91) *	3
	Larynx	0.45 ± 0.21	0.52 ± 0.14 (0.44) *	3.13 ± 1.18	3.06 ± 1.08 (3.59) *	2.4
	Liver	0.85 ± 0.11	0.93 ± 0.06 (0.89) *	5.30 ± 4.79	2.00 ± 1.79 (3.54) *	3
	Lung_L	0.95 ± 0.02	0.96 ± 0.02 (0.95) *	0.90 ± 0.39	0.77 ± 0.37 (0.90) *	3
	Lung_R	0.95 ± 0.03	0.96 ± 0.02 (0.95) *	1.11 ± 0.58	0.89 ± 0.43 (1.07) *	3
	Musc_Constrict	0.41 ± 0.16	0.45 ± 0.16 (0.33) *	2.22 ± 1.86	2.07 ± 1.52 (3.11) *	2
	Pancreas	0.17 ± 0.19	0.41 ± 0.24 (0.24) *	15.18 ± 18.92	8.68 ± 11.12 (22.23)	2.25
	SpinalCord	0.66 ± 0.16	0.66 ± 0.16 (0.62) *	1.47 ± 0.88	1.41 ± 0.63 (1.62) *	2.75
	Stomach	0.46 ± 0.21	0.79 ± 0.19 (0.70) *	10.47 ± 6.72	2.33 ± 2.12 (4.62)	3
	Trachea	0.67 ± 0.17	0.74 ± 0.16	1.22 ± 0.61	0.88 ± 0.54	3

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4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
			(0.65) *		(1.17) *	
	LN_Ax_L1_L	0.59 ± 0.09	0.65 ± 0.11 (0.53) *	2.73 ± 0.81	2.58 ± 1.17 (3.90) *	3
	LN_Ax_L1_R	0.52 ± 0.12	0.58 ± 0.14 (0.46) *	3.57 ± 1.31	3.19 ± 1.61 (4.80) *	3
	LN_Ax_L2_L	0.58 ± 0.16	0.63 ± 0.16 (0.50) *	2.56 ± 1.37	2.10 ± 0.96 (3.12) *	2.67
	LN_Ax_L2_R	0.55 ± 0.20	0.60 ± 0.20 (0.46) *	2.88 ± 1.45	2.70 ± 1.77 (3.87) *	2.67
	LN_Ax_L3_L	0.55 ± 0.17	0.61 ± 0.19 (0.46) *	2.33 ± 1.38	2.15 ± 1.52 (3.36) *	3
	LN_Ax_L3_R	0.46 ± 0.16	0.50 ± 0.18 (0.36) *	2.82 ± 1.49	2.53 ± 1.41 (3.90) *	3
	LN_IMN_L	0.17 ± 0.11	0.37 ± 0.16 (0.20) *	2.66 ± 1.05	1.63 ± 0.96 (2.93) *	2.67
	LN_IMN_R	0.24 ± 0.16	0.48 ± 0.19 (0.33) *	2.55 ± 1.84	1.55 ± 1.60 (2.99) *	2.67
	LN_Sclav_L	0.60 ± 0.15	0.67 ± 0.15 (0.53) *	2.18 ± 0.72	1.87 ± 0.89 (2.64) *	2.67
	LN_Sclav_R	0.48 ± 0.09	0.55 ± 0.10 (0.44) *	2.89 ± 0.88	2.60 ± 0.85 (3.54) *	2.67
Whole Body – Physiological Uptake Organs	Bone	0.76 ± 0.08	0.87 ± 0.05 (0.75) *	3.80 ± 2.88	0.91 ± 1.02 (1.87) *	3
	Bowel	0.46 ± 0.14	0.74 ± 0.10 (0.62) *	1.32 ± 1.01	0.48 ± 0.13 (3.32)	3
	BowelBag	0.59 ± 0.14	0.75 ± 0.15 (0.68) *	10.57 ± 5.08	7.69 ± 5.07 (12.61)	3
	Brain	0.97 ± 0.01	0.97 ± 0.03 (0.96) *	18.17 ± 5.89	17.18 ± 5.24 (20.30)	3
	Cavity_Oral	0.77 ± 0.13	0.78 ± 0.12 (0.68) *	0.69 ± 0.37	0.91 ± 1.17 (1.32) *	3
	Glnd_Lacrimal_L	0.23 ± 0.17	0.37 ± 0.16 (0.24) *	3.18 ± 1.96	3.19 ± 1.66 (4.56) *	3
	Glnd_Lacrimal_R	0.24 ± 0.16	0.46 ± 0.14 (0.34) *	0.88 ± 0.51	0.72 ± 0.43 (1.13) *	3
	Glnd_Submand_L	0.58 ± 0.11	0.79 ± 0.06 (0.72) *	0.74 ± 0.39	0.81 ± 0.79 (1.36) *	3
	Glnd_Submand_R	0.55 ± 0.16	0.77 ± 0.06 (0.68) *	1.65 ± 0.53	0.81 ± 0.35 (1.14) *	3
	Heart	0.89 ± 0.04	0.91 ± 0.04	1.83 ± 0.90	0.81 ± 0.38	3

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4.1.0 CT Model:	Structure:	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
			(0.87) *		(1.38) *	
	Kidney_L	0.72 ± 0.17	0.93 ± 0.04 (0.84) *	3.10 ± 0.84	2.65 ± 0.93 (3.42) *	3
	Kidney_R	0.73 ± 0.19	0.92 ± 0.07 (0.82) *	3.76 ± 2.43	0.90 ± 0.51 (2.14) *	3
	Liver	0.84 ± 0.12	0.93 ± 0.07 (0.87) *	3.74 ± 2.91	0.85 ± 0.44 (2.34) *	3
	LN_Iliac	0.63 ± 0.04	0.71 ± 0.03 (0.68) *	5.28 ± 3.59	2.26 ± 3.82 (4.41) *	3
	Parotid_L	0.71 ± 0.09	0.81 ± 0.05 (0.77) *	2.59 ± 0.56	1.59 ± 0.33 (1.97) *	3
	Parotid_R	0.71 ± 0.09	0.82 ± 0.05 (0.78) *	1.97 ± 0.65	1.30 ± 0.47 (1.62) *	3
	Prostate	0.71 ± 0.14	0.85 ± 0.05 (0.76) *	2.08 ± 0.71	1.34 ± 0.56 (1.70) *	3
	Spleen	0.72 ± 0.10	0.95 ± 0.01 (0.87) *	3.21 ± 1.54	1.55 ± 0.61 (2.53) *	3

Mean ± Std Dice coefficient (lower 95th percentile confidence bound based on normal distribution in parentheses)
** Equivalence demonstrated at p=0.05 significance level between Contour ProtégéAI and MIM Atlas*
† Comparisons for both atlas and Contour ProtégéAI calculated only on axial slices that contained the ground truth.

Additionally, preliminary user evaluation conducted as part of testing demonstrated that Contour ProtégéAI yields comparable time-saving functionality when creating contours as other commercially available automatic segmentation products.

Table 3: 4.1.0 CT models cumulative APL in mm

4.1.0 CT Models:	MIM Atlas	Contour ProtégéAI
Head and Neck	38.69 ± 33.36	28.61 ± 29.59 (31.61) *
Thorax	89.24 ± 82.73	65.44 ± 68.85 (72.54) *
Whole Body - Physiological Uptake Organs	138.06 ± 142.42	98.20 ± 127.11 (118.75) *

Mean ± Std APL mm (upper 95th percentile confidence bound based on normal distribution in parentheses)
** Equivalence demonstrated at p=0.05 significance level between Contour ProtégéAI and MIM Atlas*

Table 4: 4.1.0 CT models localization accuracy

4.1.0 CT Models:	Structure:	Relevant FOV	Whole Body CT
Head and Neck	Bone_Mandible	100	100
	BrachialPlex_L	100	91
	BrachialPlex_R	100	95

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4.1.0 CT Models:	Structure:	Relevant FOV	Whole Body CT
	Brain	100	100
	Brainstem	100	100
	Cavity_Oral	100	100
	Cochlea_L	95	95
	Cochlea_R	96	95
	Eye_L	100	100
	Eye_R	100	100
	Glnd_Lacrimal_L	98	100
	Glnd_Lacrimal_R	100	100
	Glnd_Submand_L	100	100
	Glnd_Submand_R	100	100
	Glnd_Thyroid	98	95
	Lens_L	97	100
	Lens_R	97	95
	Lips	100	95
	OpticChiasm	80	91
	OpticNrv_L	99	100
	OpticNrv_R	99	100
	Parotid_L	99	100
	Parotid_R	100	100
	Pituitary	100	86
	SpinalCord	99	100
	LN_Neck_IA	100	100
	LN_Neck_IB_L	100	100
	LN_Neck_IB_R	100	100
	LN_Neck_IIA_L	100	100
	LN_Neck_IIA_R	100	95
	LN_Neck_IIB_L	100	100
	LN_Neck_IIB_R	100	95
	LN_Neck_III_L	100	100

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4.1.0 CT Models:	Structure:	Relevant FOV	Whole Body CT
	LN_Neck_III_R	100	100
	LN_Neck_IV_L	100	100
	LN_Neck_IV_R	100	95
	LN_Neck_V_L	100	100
	LN_Neck_V_R	100	91
	LN_Neck_VIA	100	100
	LN_Retropharynx_L	100	100
	LN_Retropharynx_R	95	100
	LN_Retrostyloid_L	100	100
	LN_Retrostyloid_R	100	100
Thorax	BrachialPlex_L	100	100
	BrachialPlex_R	100	100
	Breast_L	100	100
	Breast_R	96	91
	Bronchus	100	100
	Carina	98	100
	Cricoid	67	100
	Esophagus	100	100
	Glnd_Thyroid	100	100
	GreatVes	100	100
	Heart	100	100
	Humerus_Head_L	100	95
	Humerus_Head_R	100	100
	Kidney_L	97	91
	Kidney_R	97	95
	Larynx	99	95
	Liver	100	100
	Lung_L	100	100
	Lung_R	100	100
	Musc_Constrict	100	91

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4.1.0 CT Models:	Structure:	Relevant FOV	Whole Body CT
	Pancreas	54	91
	SpinalCord	100	100
	Stomach	100	100
	Trachea	99	100
	LN_Ax_L1_L	100	100
	LN_Ax_L1_R	100	100
	LN_Ax_L2_L	100	100
	LN_Ax_L2_R	100	100
	LN_Ax_L3_L	100	100
	LN_Ax_L3_R	100	100
	LN_IMN_L	100	100
	LN_IMN_R	100	100
	LN_Sclav_L	100	100
	LN_Sclav_R	100	100
Whole Body - Physiological Uptake Organs	Bladder	N/A	95
	Bone	N/A	100
	Bowel	N/A	100
	BowelBag	N/A	100
	Brain	N/A	100
	Cavity_Oral	N/A	100
	Glnd_Lacrimal_L	N/A	100
	Glnd_Lacrimal_R	N/A	100
	Glnd_Submand_L	N/A	100
	Glnd_Submand_R	N/A	100
	Heart	N/A	100
	Kidney_L	N/A	95
	Kidney_R	N/A	100
	Liver	N/A	100
	LN_Iliac	N/A	64

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4.1.0 CT Models:	Structure:	Relevant FOV	Whole Body CT
	Parotid_L	N/A	100
	Parotid_R	N/A	100
	Prostate	N/A	100
	Spleen	N/A	100

Percentage of images that were successfully localized by Contour ProtégéAI. N/A (not applicable) refers to models which the relevant FOV is a Whole Body CT.

Known Limitations and Biases:

Contour ProtégéAI can produce incorrect or implausible segmentations when the underlying anatomy is in the field of view of the scan but not clearly discernable due to image quality, noise, or the generally low contrast of some structures. This can occur in any situation where the organ at risk is not clearly discernable in the image, but has been observed for submandibular glands, optic nerves, and optic chiasm, in particular.

While both images with and without IV contrast are represented in the training set for Contour ProtégéAI, the effect of iodinated contrast can vary due to patient weight, contrast dosage, and time since injection. In cases where there is unusually intense brain enhancement, the posterior boundary of the brain can be incorrectly segmented.

The age breakdown of the training data, where patient age was available, was predominantly in the 40-60 and 60+ age ranges. While this is appropriate to the intended patient population, only a small proportion of testing and training data was for patients under 40, so more intensive review may be warranted for younger patients.

Where patient sex was available, the ratio of male to female patients in the training set was roughly 2:1. The testing data was chosen with a more even ratio (about 0.82:1) to establish applicability of the model to both.

Conclusion

Based on the Discussion and Testing and Performance Data above, the proposed device is determined to be as safe and effective as its predicate device, Contour ProtégéAI 510 K223774. In addition, the proposed device performs as well as the reference predicate device, MIM 4.1 SEASTAR (tradename MIM Maestro) K071964.

References

[1] Vaassen, F. *et al.* Evaluation of measures for assessing time-saving of automatic organ-at-risk segmentation in radiotherapy. *Physics and Imaging in Radiation Oncology* 13, 1–6 (2020).