MIM Software Inc.
% Lynn Hanigan
Quality Assurance Director
25800 Science Park Drive
Suite 180
CLEVELAND OH 44122

April 6, 2023

Re: K223774
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: March 9, 2023
Received: March 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 (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: 2023.04.06 19:24:44 -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

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)*
K223774

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.

25800 Science Park Drive - Suite 180
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: Dec 14, 2022

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 -	K213976	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:

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

- 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.

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 326 CT images from 37 clinical sites across multiple continents was gathered for the training of the final neural network models. The following table lists the data used for the training of the final production models.

CT data used to train the final production of the 4.0.0 CT models

Institution	Country	# of images
Institution 1	USA	2
Institution 2	USA	5
Institution 3	USA	11
Institution 4	USA	4
Institution 5	USA	3
Institution 6	USA	1
Institution 7	USA	31
Institution 8	USA	12
Institution 9	USA	6
Institution 10	Hong Kong	25
Institution 11	USA	10
Institution 12	USA	6
Institution 13	USA	10
Institution 14	USA	6
Institution 15	USA	21
Institution 16	USA	2

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

Institution	Country	# of images
Institution 17	USA	10
Institution 18	USA	7
Institution 19	USA	11
Institution 20	USA	22
Institution 21	USA	6
Institution 22	USA	21
Institution 23	Australia	15
Institution 24	USA	10
Institution 25	USA	11
Institution 26	USA	10
Institution 27	USA	2
Institution 28	USA	1
Institution 29	USA	7
Institution 30	USA	6
Institution 31	USA	4
Institution 32	USA	1
Institution 33	USA	2
Institution 34	USA	2
Institution 35	USA	6
Institution 36	USA	14
Institution 37	USA	3

Substantial Equivalence

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Clearance Dates	TBD	02/03/2022	9/26/2007

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	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 applications including, but not limited to, quantitative analysis, aiding adaptive

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
			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 normal structures across a variety of CT anatomical locations. • And segmenting the prostate, the seminal vesicles, and the urethra within T2-weighted MR images.	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 normal structures across a variety of CT anatomical locations. • And segmenting normal structures of the prostate, seminal vesicles, and urethra within T2-weighted MR images.	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 and DICOM objects. • Create, display and print reports from medical images. • Registration, fusion display, and review of medical images for diagnosis, treatment

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.	Appropriate image visualization software must be used to review and, if necessary, edit results automatically generated by Contour ProtégéAI.	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.
Modalities	CT and MR	CT and MR	CT, MR, CR, DX, MG, US, SPECT, PET and XA
Atlas-Based Segmentation	No	No	Yes

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
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	Yes

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Previous 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 ***(3.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Abdomen CT Lungs and Liver CT MRT Additional Structures 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	None

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

ITEM	Contour ProtégéAI (K# - TBD)	Contour ProtégéAI (K213976)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
New Neural Network Models included	**(4.0.0 models)** Head and Neck CT Thorax CT Abdomen CT Pelvis CT SurePlan MRT CT		

Discussion

Changes within this submission include new 4.0.0 CT neural network models with additional contours. These changes differ when comparing to Contour ProtégéAI 510(K)213976. 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

For the proposed Contour ProtégéAI device, the new 4.0.0 CT neural network models were trained on a pool of training data that did not include any patients from the same institution as the test subjects. This training data included 326 CT images gathered from 37 clinical sites across multiple countries. Models were trained using images of adults at various ages. No ethnicities or genders were excluded from training. The models were then evaluated on the test subjects from a pool of 819 independent images gathered from 10 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

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

additional time to ensure the highest quality training data. In particular, the consultants were asked to contour all specified OAR structures on all images to 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 predicate MIM device was configured with Atlases built from the same training data used to train the models. We tested Contour ProtégéAI against the predicate device, and the goal of this testing is to show that it is equivalent or superior to the predicate. The performance of both segmentation devices was measured by calculating the Dice score of the novel segmentations with the original ground-truth contours. Any structure that ends up being statistically significantly worse than MIM atlas segmentation predicate device will be removed from the final model.

The mean and standard deviation Dice coefficients, 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:

4.0.0 CT Model:	Structure:	MIM Atlas	Contour ProtégéAI
Head and Neck	Bone_Mandible	0.81 ± 0.07	0.85 ± 0.07 (0.82) *
	BrachialPlex_L	0.17 ± 0.08	0.26 ± 0.10 (0.19) *
	BrachialPlex_R	0.15 ± 0.07	0.25 ± 0.11 (0.16) *
	Brain	0.97 ± 0.01	0.98 ± 0.01 (0.97) *
	Brainstem	0.78 ± 0.09	0.82 ± 0.09 (0.78) *
	Cavity_Oral	0.75 ± 0.14	0.77 ± 0.12 (0.69) *
	Cochlea_L	0.19 ± 0.15	0.27 ± 0.17 (0.20) *
	Cochlea_R	0.17 ± 0.15	0.29 ± 0.18 (0.21) *
	Eye_L	0.80 ± 0.08	0.87 ± 0.06 (0.84) *
	Eye_R	0.80 ± 0.10	0.87 ± 0.06 (0.83) *
	Glnd_Lacrimal_L	0.22 ± 0.17	0.39 ± 0.17 (0.27) *
	Glnd_Lacrimal_R	0.23 ± 0.16	0.43 ± 0.15 (0.32) *
	Glnd_Submand_L	0.57 ± 0.13	0.77 ± 0.10 (0.69) *
	Glnd_Submand_R	0.56 ± 0.16	0.77 ± 0.09 (0.68) *

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

4.0.0 CT Model:	Structure:	MIM Atlas	Contour ProtégéAI
	Glnd_Thyroid	0.47 ± 0.18	0.71 ± 0.16 (0.59) *
	Lens_L	0.22 ± 0.23	0.61 ± 0.17 (0.52) *
	Lens_R	0.22 ± 0.22	0.63 ± 0.15 (0.54) *
	Lips	0.38 ± 0.14	0.38 ± 0.14 (0.28) *
	OpticChiasm	0.04 ± 0.07	0.12 ± 0.11 (0.08) *
	OpticNrv_L	0.45 ± 0.15	0.53 ± 0.13 (0.46) *
	OpticNrv_R	0.44 ± 0.14	0.52 ± 0.12 (0.45) *
	Parotid_L	0.71 ± 0.10	0.80 ± 0.10 (0.75) *
	Parotid_R	0.71 ± 0.09	0.80 ± 0.06 (0.77) *
	Pituitary	0.38 ± 0.18	0.49 ± 0.15 (0.37) *
	SpinalCord	0.66 ± 0.14	0.63 ± 0.16 (0.57) *
Thorax	BrachialPlex_L	0.28 ± 0.14	0.37 ± 0.13 (0.25) *
	BrachialPlex_R	0.28 ± 0.11	0.36 ± 0.16 (0.23) *
	Breast_L	0.75 ± 0.10	0.74 ± 0.17 (0.65) *
	Breast_R	0.76 ± 0.11	0.77 ± 0.10 (0.71) *
	Bronchus	0.60 ± 0.17	0.66 ± 0.13 (0.56) *
	Carina	0.39 ± 0.18	0.51 ± 0.13 (0.43) *
	Cricoid	0.03 ± 0.05	0.03 ± 0.04 (-0.01) *
	Esophagus	0.49 ± 0.16	0.70 ± 0.15 (0.65) *
	Glnd_Thyroid	0.46 ± 0.18	0.67 ± 0.16 (0.57) *
	GreatVes	0.70 ± 0.08	0.74 ± 0.10 (0.65) *
	Heart	0.88 ± 0.08	0.90 ± 0.07 (0.88) *
	Humerus_Head_L	0.95 ± 0.02	0.95 ± 0.02 (0.94) * †
	Humerus_Head_R	0.93 ± 0.09	0.96 ± 0.02 (0.90) * †
	Kidney_L	0.74 ± 0.18	0.92 ± 0.05 (0.85) *
	Kidney_R	0.74 ± 0.19	0.91 ± 0.06 (0.84) *
	Larynx	0.45 ± 0.21	0.50 ± 0.16 (0.42) *
	Liver	0.85 ± 0.11	0.93 ± 0.06 (0.89) *

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

4.0.0 CT Model:	Structure:	MIM Atlas	Contour ProtégéAI
	Lung_L	0.95 ± 0.02	0.96 ± 0.02 (0.96) *
	Lung_R	0.95 ± 0.03	0.96 ± 0.02 (0.96) *
	Musc_Constrict	0.41 ± 0.16	0.47 ± 0.15 (0.37) *
	Pancreas	0.17 ± 0.19	0.45 ± 0.22 (0.32) *
	SpinalCord	0.67 ± 0.16	0.66 ± 0.16 (0.62) *
	Stomach	0.46 ± 0.21	0.80 ± 0.16 (0.72) *
	Trachea	0.67 ± 0.17	0.73 ± 0.17 (0.65) *
Abdomen	Bladder	0.72 ± 0.23	0.91 ± 0.12 (0.81) *
	Bowel	0.46 ± 0.14	0.73 ± 0.11 (0.61) * †
	BowelBag	0.63 ± 0.08	0.68 ± 0.08 (0.62) * †
	CaudaEquina	0.62 ± 0.15	0.66 ± 0.13 (0.55) *
	Kidney_L	0.74 ± 0.17	0.93 ± 0.03 (0.84) *
	Kidney_R	0.75 ± 0.18	0.92 ± 0.05 (0.82) *
	Liver	0.84 ± 0.12	0.92 ± 0.08 (0.86) *
	SpinalCord	0.60 ± 0.16	0.63 ± 0.13 (0.55) *
	Stomach	0.49 ± 0.21	0.81 ± 0.11 (0.70) *
Pelvis	Bladder	0.73 ± 0.22	0.93 ± 0.11 (0.89) *
	Bowel	0.37 ± 0.15	0.52 ± 0.19 (0.41) *
	Colon_Sigmoid	0.20 ± 0.17	0.60 ± 0.26 (0.48) *
	Femur_Head_L	0.90 ± 0.08	0.93 ± 0.05 (0.91) *
	Femur_Head_R	0.90 ± 0.08	0.93 ± 0.04 (0.91) *
	LN_Iliac	0.63 ± 0.04	0.72 ± 0.03 (0.68) *
	PenileBulb	0.59 ± 0.16	0.63 ± 0.16 (0.58) *
	Prostate	0.74 ± 0.12	0.85 ± 0.06 (0.82) *
	Rectum	0.63 ± 0.18	0.83 ± 0.11 (0.79) *
	Sacrum	0.87 ± 0.01	0.92 ± 0.00 (0.87) *
	SeminalVes	0.38 ± 0.27	0.68 ± 0.15 (0.61) *
SurePlan MRT	Bone	0.76 ± 0.08	0.87 ± 0.05 (0.74) *

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

4.0.0 CT Model:	Structure:	MIM Atlas	Contour ProtégéAI
	Glnd_Lacrimal_L	0.23 ± 0.16	0.30 ± 0.22 (0.14) *
	Glnd_Lacrimal_R	0.24 ± 0.16	0.33 ± 0.23 (0.17) *
	Glnd_Submand_L	0.58 ± 0.11	0.77 ± 0.13 (0.68) *
	Glnd_Submand_R	0.55 ± 0.16	0.77 ± 0.14 (0.65) *
	Glnd_Thyroid	0.48 ± 0.18	0.61 ± 0.18 (0.48) *
	Kidney_L	0.72 ± 0.18	0.89 ± 0.04 (0.79) *
	Kidney_R	0.76 ± 0.17	0.89 ± 0.04 (0.80) *
	Liver	0.85 ± 0.12	0.93 ± 0.07 (0.88) *
	Lung_L	0.94 ± 0.03	0.95 ± 0.03 (0.92) *
	Lung_R	0.94 ± 0.05	0.95 ± 0.04 (0.91) *
	Parotid_L	0.70 ± 0.09	0.80 ± 0.05 (0.76) *
	Parotid_R	0.71 ± 0.09	0.82 ± 0.05 (0.77) *
	Spleen	0.72 ± 0.10	0.95 ± 0.03 (0.87) *

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.

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 K213976. In addition, the proposed device performs as well as the reference device, MIM 4.1 SEASTAR (tradename MIM Maestro) K071964.