



MIM Software Inc.
Sydney Lindner
Regulatory Affairs Engineer
25800 Science Park Drive, Suite 180
Cleveland, Ohio 44122

February 3, 2025

Re: K250035

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: January 7, 2025
Received: January 7, 2025

Dear Sydney Lindner:

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 that reads "Lora D. Weidner". The signature is written in a cursive style. A large, semi-transparent blue "FDA" watermark is visible 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)

K250035

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 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.

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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510(k) Summary

(The following information is in conformance with 21 CFR 807.92)

Submitter

K250035

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

Phone: 216-455-0600

Fax: 216-455-0601

Contact Person: Sydney Lindner

Date Summary Prepared: January 7, 2025

Device Name

Trade Name: Contour ProtégéAI+

Common Name: Medical Imaging Software

Regulation Number / Product Code: 21 CFR 892.2050 Product Code QKB

Classification Name: System, Imaging Processing,
Radiological

Predicate and Reference Devices

Predicate:	K231765	Contour ProtégéAI	MIM Software Inc.
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Reference:	K071964	MIM 4.1 (SEASTAR) [i.e., MIM Maestro]	MIMvista Corp.
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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.

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 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.

Indications for use have not been modified. The intended use is the same as the last 510(k) clearance for Contour ProtégéAI (K231765).

In the upcoming 1.4.0 release, one new neural network model is being added and three existing neural network models are being updated by retraining with additional or updated contours which prompted this premarket submission of the subject device.

Table 1 – Comparison to Predicate Device.

ITEM	Subject Device: Contour ProtégéAI+ (K250035)	Predicate Device: Contour ProtégéAI (K231765)	Substantial Equivalence Discussion
Clearance Date	TBD	November 8, 2023	N/A
Operating Platform	Server-based application supporting: <ul style="list-style-type: none"> • Linux-based OS • Local deployment on Windows or Mac 	Server-based application supporting: <ul style="list-style-type: none"> • Linux-based OS • Local deployment on Windows or Mac 	No change
Modalities	CT and MR	CT and MR	No change
Atlas-based Segmentation	No	No	No change
Automatically contour imaging data using machine-learning	Yes	Yes	No change
Cloud-based Deployment	Yes	Yes	No change
Local Deployment or Installation	Yes	Yes	No change
Neural	(1.0.0 models)	(1.0.0 models)	The subject device contains

ITEM	Subject Device: Contour ProtégéAI+ (K250035)	Predicate Device: Contour ProtégéAI (K231765)	Substantial Equivalence Discussion
Network Models Included	<ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Liver CT • Prostate MR <p>(1.1.0 model)</p> <ul style="list-style-type: none"> • Prostate MR <p>(2.0.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Abdomen CT • Lungs and Liver CT <p>(3.1.0 models)*</p> <ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Abdomen CT • Lungs and Liver CT • MRT Additional Structures CT <p>(4.0.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Thorax CT • Abdomen CT • Pelvis CT • SurePlan MRT CT <p>(4.1.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Thorax CT • Whole Body – Physiological • Uptake Organs CT <p>(4.2.0 models)</p>	<ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Liver CT • Prostate MR <p>(1.1.0 model)</p> <ul style="list-style-type: none"> • Prostate MR <p>(2.0.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Abdomen CT • Lungs and Liver CT <p>(3.1.0 models)*</p> <ul style="list-style-type: none"> • Head and Neck CT • Prostate CT • Thorax CT • Abdomen CT • Lungs and Liver CT • MRT Additional Structures CT <p>(4.0.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Thorax CT • Abdomen CT • Pelvis CT • SurePlan MRT CT <p>(4.1.0 models)</p> <ul style="list-style-type: none"> • Head and Neck CT • Thorax CT • Whole Body – Physiological • Uptake Organs CT 	<p>one new neural network model and three updated neural network models compared to the predicate. These 4 models were all trained on the same architecture as the predicate without any changes. These 4 models cover all the existing structures for contouring and additional, new structures, which are denoted in bold font.</p> <p>These 4 models were all tested according to the same procedures and acceptance criteria as the predicate. No unexpected results were observed. The changes do not raise new questions for safety and effectiveness.</p>

ITEM	Subject Device: Contour ProtégéAI+ (K250035)	Predicate Device: Contour ProtégéAI (K231765)	Substantial Equivalence Discussion
	<ul style="list-style-type: none"> • Thorax CT <ul style="list-style-type: none"> - LN_IMN_L - LN_IMN_R - LN_Sclav_L - LN_Sclav_R - LN_Ax_L1_L - LN_Ax_L1_R - LN_Ax_L2_L - LN_Ax_L2_R - LN_Ax_L3_L - LN_Ax_L3_R - BrachialPlex_L*** - BrachialPlex_R*** - Breast_L*** - Breast_R*** - Breast_L_RTOG** - Breast_R_RTOG** - Bronchus - Carina - Cricoid - Esophagus - GlnD_Thyroid - GreatVes*** - Heart*** - Humerus_Head_L - Humerus_Head_R - Kidney_L - Kidney_R - Larynx*** - Liver - Lung_L - Lung_R - Musc_Constrict - Pancreas - SpinalCord - Stomach*** - Trachea - Ribs** - Chestwall_L** - Chestwall_R** - A_Asc_Aorta** - A_LAD** • Abdomen CT <ul style="list-style-type: none"> - Bladder - Bowel*** 		

ITEM	Subject Device: Contour ProtégéAI+ (K250035)	Predicate Device: Contour ProtégéAI (K231765)	Substantial Equivalence Discussion
	<ul style="list-style-type: none"> - Bowel Bag*** - Cauda Equina - Left Kidney - Right Kidney - Liver - Spinal Cord - Stomach*** • Female Pelvis CT** <ul style="list-style-type: none"> - Bowel Bag** - Bowel** - LN Pelvics** - Bladder** - Uterocervix** - Colon Sigmoid** - Cauda Equina** - Sacral Plexus** - Sacrum** - Rectum** - Femur Head L** - Femur Head R** • SurePlan MRT CT <ul style="list-style-type: none"> - Bone*** - GlnD_Lacrimal_L - GlnD_Lacrimal_R - GlnD_Submand_L - GlnD_Submand_R - GlnD_Thyroid - Kidney_L (Kidney_L w/o Renal Pelvis) - Kidney_R (Kidney_R w/o Renal Pelvis) - Liver - Lung_L - Lung_R - Parotid_L - Parotid_R - Spleen 		

* The 3.1.0 models share the same training images and architecture as the 3.0.0 models. Some errors and style inconsistencies in the training segmentations were corrected before re-training, resulting in the 3.1.0 models.

** Indicates new contour/model.

*** Indicates updated contour.

Testing and Performance Data

Changes within this submission compared to the predicate device, Contour ProtégéAI (K231765), include one new 4.2.0 neural network model and three updated 4.2.0 neural network models with additional or updated contours. Non-inferiority testing was used to compare the Contour ProtégéAI+ subject device to Atlases created from the MIM Maestro (K071964) reference device.

Verification and validation tests were performed for each of the core features of Contour ProtégéAI+:

- *Contour creation time savings*
- *Clinical quality contour generation*

The testing methods include both internal verification by MIM Software's own qualified testers and external validation by trained medical professionals.

The Contour ProtégéAI+ subject device was evaluated on the test subjects from a pool of 770 images gathered from 32 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 radiation oncologists against the same standards and guidelines. Qualified staff at MIM Software (MD 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 the treatment position ("simulation CT"). Series that were no-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 datasets used to train each model in the Contour ProtégéAI+ device. The MIM Maestro (K071964) reference device was configured with Atlases built from the same training data used to train the models. We tested Contour ProtégéAI+ against the reference device, and the goal of this testing is to show that the subject device is equivalent or superior to the reference device. 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 qualitatively 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 (APL) 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 as well as in our User Guide and White Paper to allow the user to better understand the performance of the device.

Across the testing data images, 53.4% were female, 31.3% were male, and 15.3% were unknown for sex. The manufacturer was GE for 43.2%, Siemens for 21.7%, Phillips for 15.5%, Toshiba for 0.4%, and unknown or other scanner vendors for 19.2%. 0.3% were between the ages of 0-20, 4.7% were between the ages of 20-40, 20.9% were between 40-60, and 50.0% were over the age of 60. 24.1% were unknown for age.

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 below.

Table 2 – Dice, MDA, and external evaluation results.

4.2.0 CT Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
Thorax	BrachialPlex_L	0.30 ± 0.14	0.41 ± 0.15 (0.28) *	3.01 ± 1.19	2.89 ± 1.07 (3.94) *	2.43
	BrachialPlex_R	0.31 ± 0.12	0.39 ± 0.15 (0.26) *	3.08 ± 1.54	3.11 ± 1.38 (4.55) *	2.43
	Breast_L	0.74 ± 0.11	0.79 ± 0.07 (0.73) *	5.73 ± 3.10	5.00 ± 2.53 (6.98) *	2.38
	Breast_R	0.76 ± 0.12	0.80 ± 0.11 (0.71) *	5.03 ± 2.72	4.49 ± 2.02 (6.24) *	2.57
	Breast_L_RT OG	0.74 ± 0.11	0.77 ± 0.11 (0.69) *	5.73 ± 3.10	5.47 ± 3.72 (7.87)	2.5
	Breast_R_RT OG	0.76 ± 0.12	0.77 ± 0.15 (0.67) *	5.03 ± 2.72	5.10 ± 3.17 (7.24)	2.5
	Bronchus	0.57 ± 0.19	0.62 ± 0.14 (0.50) **	2.69 ± 2.22	1.86 ± 0.90 (3.19) *	2.63
	Carina	0.37 ± 0.18	0.50 ± 0.12 (0.41) *	2.67 ± 2.65	1.93 ± 0.83 (3.07) *	2.43
	Cricoid	0.02 ± 0.04	0.06 ± 0.05 (0.02) *	4.77 ± 1.53	5.01 ± 1.40 (6.27) *	2.86
	Esophagus	0.47 ± 0.17	0.69 ± 0.16 (0.63) *	2.73 ± 2.19	1.08 ± 1.53 (1.71) *	2.5
	GlnD_Thyroid	0.46 ± 0.18	0.66 ± 0.18 (0.53) *	2.84 ± 1.90	1.68 ± 1.44 (2.86) *	2.86
	GreatVes	0.64 ± 0.17	0.70 ± 0.16 (0.53) **	4.59 ± 1.99	3.44 ± 1.99 (5.46) *	2.63
	Heart	0.88 ± 0.08	0.90 ± 0.07 (0.87) *	3.05 ± 2.03	2.49 ± 1.84 (3.08) *	2.63
	Humerus_Head_L	0.60 ± 0.24	0.62 ± 0.24 (0.42) **	0.38 ± 0.23	0.33 ± 0.22 (0.52) *	3
	Humerus_Head_R	0.57 ± 0.22	0.60 ± 0.22 (0.41) **	0.78 ± 2.00	0.33 ± 0.35 (1.60) *	3

4.2.0 CT Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	Kidney_L	0.73 ± 0.19	0.90 ± 0.09 (0.83) *	3.75 ± 2.66	1.32 ± 1.13 (2.27) *	2.75
	Kidney_R	0.73 ± 0.19	0.89 ± 0.09 (0.83) *	3.97 ± 2.60	1.41 ± 1.06 (2.34) *	2.75
	Larynx	0.47 ± 0.19	0.59 ± 0.14 (0.51) *	3.42 ± 1.32	2.87 ± 1.34 (3.51) *	2.63
	Liver	0.84 ± 0.12	0.90 ± 0.13 (0.85) *	5.06 ± 4.18	3.56 ± 9.12 (6.39) *	2.71
	Lung_L	0.95 ± 0.02	0.96 ± 0.02 (0.96) *	1.12 ± 0.46	0.79 ± 0.40 (0.94) *	2.75
	Lung_R	0.95 ± 0.03	0.97 ± 0.03 (0.96) *	1.36 ± 0.67	0.85 ± 0.48 (1.04) *	2.75
	Musc_Constrict	0.40 ± 0.17	0.50 ± 0.17 (0.39) *	2.00 ± 1.79	1.67 ± 1.55 (2.71) *	3
	Pancreas	0.17 ± 0.17	0.47 ± 0.21 (0.36) *	16.43 ± 16.42	6.80 ± 8.89 (14.66) **	2.17
	SpinalCord	0.66 ± 0.16	0.64 ± 0.17 (0.59) *	1.29 ± 0.91	1.28 ± 0.72 (1.50) *	2.5
	Stomach	0.46 ± 0.22	0.73 ± 0.21 (0.64) *	12.56 ± 13.48	6.89 ± 20.57 (14.36) **	2.13
	Trachea	0.68 ± 0.15	0.74 ± 0.17 (0.66) *	1.43 ± 0.65	1.12 ± 0.64 (1.46) *	2.63
	A_LAD	0.07 ± 0.09	0.32 ± 0.12 (0.22) *	8.77 ± 10.69	3.43 ± 4.46 (11.41) **	2.67
	A_Aorta_Asc	0.72 ± 0.16	0.83 ± 0.17 (0.68) **	2.90 ± 2.16	1.11 ± 0.60 (2.64) *	2.14
	Rib	0.25 ± 0.09	0.28 ± 0.11 (0.21) *	35.64 ± 12.65	39.04 ± 14.62 (49.68) **	2.63
	Chestwall_L	0.40 ± 0.16	0.39 ± 0.17 (0.19) **	4.35 ± 1.12	4.44 ± 1.24 (5.87) *	2.43
	Chestwall_R	0.45 ± 0.18	0.42 ± 0.18 (0.22) **	4.66 ± 1.65	4.69 ± 1.56 (6.51) *	2.43
	LN_Ax_L1_L	0.59 ± 0.09	0.63 ± 0.10 (0.75) *	2.76 ± 0.89	2.25 ± 0.80 (3.32) *	2.67

4.2.0 CT Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	LN_Ax_L1_R	0.52 ± 0.12	0.58 ± 0.13 (0.69) *	3.46 ± 1.04	2.90 ± 1.52 (4.09) *	2.67
	LN_Ax_L2_L	0.57 ± 0.16	0.64 ± 0.13 (0.77) **	2.57 ± 1.25	1.93 ± 0.88 (2.88) *	2.67
	LN_Ax_L2_R	0.53 ± 0.20	0.60 ± 0.18 (0.73) **	2.91 ± 1.29	2.44 ± 1.26 (3.31) *	2.67
	LN_Ax_L3_L	0.55 ± 0.17	0.62 ± 0.19 (0.76) **	2.21 ± 1.11	1.90 ± 1.26 (2.87) *	2.67
	LN_Ax_L3_R	0.46 ± 0.16	0.52 ± 0.17 (0.65) *	3.30 ± 1.95	2.74 ± 1.73 (4.24) *	2.67
	LN_IMN_L	0.17 ± 0.11	0.41 ± 0.17 (0.59) *	4.75 ± 3.26	1.82 ± 0.85 (5.05) **	3
	LN_IMN_R	0.23 ± 0.16	0.48 ± 0.20 (0.63) *	3.36 ± 1.95	1.69 ± 1.38 (3.09) *	3
	LN_Sclav_L	0.58 ± 0.15	0.66 ± 0.13 (0.79) *	2.84 ± 1.94	2.49 ± 1.70 (4.18) *	2
	LN_Sclav_R	0.48 ± 0.09	0.55 ± 0.09 (0.64) *	2.97 ± 0.75	2.67 ± 0.90 (3.56) *	2.33
Abdomen	Bladder	0.72 ± 0.23	0.92 ± 0.16 (0.81) *	3.97 ± 3.00	0.78 ± 0.73 (1.93) *	2.6
	Bowel	0.34 ± 0.14	0.52 ± 0.19 (0.37) *	9.26 ± 3.49	5.05 ± 3.17 (8.13) **	2.5
	BowelBag	0.30 ± 0.09	0.36 ± 0.11 (0.29) *	14.13 ± 3.62	10.08 ± 3.36 (12.50) *	2.89
	CaudaEquina	0.62 ± 0.15	0.69 ± 0.13 (0.59) *	1.17 ± 0.51	0.95 ± 0.53 (1.33) *	2.6
	Kidney_L	0.74 ± 0.17	0.94 ± 0.03 (0.85) *	3.86 ± 2.48	0.82 ± 0.41 (2.12) *	2.9
	Kidney_R	0.75 ± 0.18	0.92 ± 0.07 (0.83) *	3.97 ± 3.35	0.96 ± 0.62 (2.74) *	2.9
	Liver	0.84 ± 0.12	0.93 ± 0.08 (0.86) *	5.23 ± 3.65	2.01 ± 2.14 (3.85) *	2.8
	SpinalCord	0.60 ± 0.16	0.65 ± 0.14 (0.56) *	1.13 ± 0.60	0.83 ± 0.32 (1.10) *	2.9

4.2.0 CT Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	Stomach	0.49 ± 0.21	0.82 ± 0.11 (0.72) *	11.56 ± 14.68	2.68 ± 2.02 (9.37) **	2.5
Female Pelvis	Bladder	0.61 ± 0.18	0.91 ± 0.06 (0.83) *	5.53 ± 3.76	1.04 ± 0.94 (2.66) *	2.75
	Bag_Bowel	0.45 ± 0.17	0.52 ± 0.20 (0.36) **	8.89 ± 2.79	6.89 ± 2.25 (9.06) *	2.63
	Bowel	0.34 ± 0.10	0.55 ± 0.19 (0.42) *	8.81 ± 3.05	4.84 ± 3.03 (7.44) *	2.75
	Colon_Sigmoid	0.05 ± 0.05	0.47 ± 0.24 (0.36) *	20.55 ± 12.23	14.72 ± 15.14 (23.56) **	2.5
	Femur_Head_L	0.86 ± 0.07	0.91 ± 0.08 (0.84) *	1.43 ± 0.78	0.95 ± 1.03 (1.75) *	2.75
	Femur_Head_R	0.87 ± 0.05	0.92 ± 0.02 (0.89) *	1.22 ± 0.59	0.69 ± 0.28 (1.09) *	2.75
	UteroCervix	0.16 ± 0.16	0.65 ± 0.27 (0.47) *	10.65 ± 5.73	4.39 ± 13.21 (13.49) **	2
	LN_Pelvics	0.64 ± 0.05	0.74 ± 0.06 (0.69) *	4.37 ± 1.11	4.12 ± 1.52 (5.28) *	2.75
	Rectum	0.38 ± 0.16	0.75 ± 0.12 (0.67) *	6.30 ± 3.30	1.52 ± 1.66 (3.04) *	2.63
	SacralPlex	0.02 ± 0.01	0.03 ± 0.01 (0.02) *	13.03 ± 1.73	12.81 ± 1.86 (14.38) *	2.5
	Sacrum	0.84 ± 0.02	0.89 ± 0.01 (0.87) *	1.58 ± 0.32	1.09 ± 0.17 (1.31) *	3
	CaudaEquina	0.65 ± 0.11	0.66 ± 0.11 (0.58) *	1.19 ± 0.58	0.94 ± 0.59 (1.39) *	2.57
SurePlan MRT	Bone	0.76 ± 0.08	0.83 ± 0.05 (0.71) *	4.77 ± 1.97	4.57 ± 3.35 (9.50) **	3
	GlnD_Lacrimal_L	0.23 ± 0.17	0.30 ± 0.21 (0.16) *	1.99 ± 0.86	1.26 ± 0.57 (1.96) *	2.67
	GlnD_Lacrimal_R	0.23 ± 0.16	0.36 ± 0.23 (0.22) *	1.53 ± 0.80	1.18 ± 0.87 (1.97) *	2.67
	GlnD_Subman	0.58 ± 0.12	0.67 ± 0.29	2.19 ±	1.00 ± 0.35	3

4.2.0 CT Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI	MDA MIM Atlas	MDA Contour ProtégéAI	External Evaluation Score
	d_L		(0.52) *	0.76	(1.45) *	
	GlnD_Subman d_R	0.56 ± 0.16	0.66 ± 0.31 (0.48) *	2.41 ± 1.14	0.97 ± 0.33 (1.68) *	3
	GlnD_Thyroid	0.47 ± 0.19	0.75 ± 0.12 (0.63) **	2.98 ± 1.95	1.29 ± 1.20 (2.46) *	2.67
	Kidney_L	0.72 ± 0.18	0.91 ± 0.04 (0.82) *	4.08 ± 2.52	1.56 ± 0.61 (2.89) *	3
	Kidney_R	0.76 ± 0.17	0.91 ± 0.03 (0.82) *	3.87 ± 3.14	1.45 ± 0.63 (3.12) *	3
	Liver	0.85 ± 0.12	0.93 ± 0.07 (0.88) *	4.82 ± 3.51	1.79 ± 1.50 (3.25) *	2.67
	Lung_L	0.94 ± 0.03	0.96 ± 0.04 (0.93) *	1.42 ± 0.51	0.90 ± 0.49 (1.32) *	3
	Lung_R	0.94 ± 0.04	0.96 ± 0.05 (0.92) *	1.66 ± 0.75	1.07 ± 0.86 (1.75) *	3
	Parotid_L	0.71 ± 0.09	0.81 ± 0.05 (0.78) *	2.17 ± 0.77	1.42 ± 0.40 (1.73) *	3
	Parotid_R	0.71 ± 0.09	0.82 ± 0.05 (0.78) *	2.17 ± 0.73	1.34 ± 0.48 (1.67) *	3
	Spleen	0.72 ± 0.10	0.95 ± 0.02 (0.87) *	4.38 ± 1.87	0.62 ± 0.45 (2.08) *	2.67

Mean ± Std MDA 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 (green)

** Equivalence was NOT demonstrated because the minimum sample size was not met for this contour (yellow)

Cells highlighted in orange indicate that equivalence was NOT demonstrated.

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 – 4.2.0 CT Models cumulative APL.

4.2.0 CT Models	MIM Atlas	Contour ProtégéAI
Thorax	220.33 ± 232.42	181.44 ± 219.43 (200.79) *
Abdomen	354.53 ± 386.05	238.05 ± 309.40 (312.07) *
Female Pelvis	433.24 ± 392.19	314.13 ± 349.77 (383.86) *
SurePlan MRT	216.52 ± 207.87	133.01 ± 160.23 (167.60) *

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 – 4.2.0 CT Models localization accuracy.

4.2.0 CT Models	Structure	Relevant FOV	Whole Body CT
Thorax	BrachialPlex_L	100	100
	BrachialPlex_R	100	100
	Breast_L	100	100
	Breast_R	100	100
	Breast_L_RTOG	100	100
	Breast_R_RTOG	100	100
	Bronchus	100	100
	Carina	99	100
	Cricoid	91	100
	Esophagus	99	100
	GlnD_Thyroid	100	77
	GreatVes	100	91
	Heart	100	100
	Humerus_Head_L	100	100
Humerus_Head_R	100	100	

4.2.0 CT Models	Structure	Relevant FOV	Whole Body CT
	Kidney_L	100	95
	Kidney_R	100	100
	Larynx	100	100
	Liver	99	95
	Lung_L	100	100
	Lung_R	100	100
	Musc_Constrict	100	91
	Pancreas	96	95
	SpinalCord	100	100
	Stomach	97	100
	Trachea	99	100
	A_LAD	100	86
	A_Aorta_Asc	96	100
	Rib	100	86
	Chestwall_L	100	100
	Chestwall_R	100	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

4.2.0 CT Models	Structure	Relevant FOV	Whole Body CT
	LN_Sclav_R	100	100
Abdomen	Bladder	98	95
	Bowel	100	100
	BowelBag	100	100
	CaudaEquina	100	100
	Kidney_L	100	91
	Kidney_R	100	100
	Liver	100	100
	SpinalCord	100	100
	Stomach	100	100
Female Pelvis	Bladder	100	100
	Bag_Bowel	100	100
	Bowel	100	100
	Colon_Sigmoid	93	86
	Femur_Head_L	100	100
	Femur_Head_R	100	95
	UteroCervix	97	100
	LN_Pelvics	100	100
	Rectum	100	100
	SacralPlex	100	100
	Sacrum	100	100
	CaudaEquina	100	100
SurePlan MRT	Bone	*	100
	GlnD_Lacrimal_L	*	100
	GlnD_Lacrimal_R	*	95

4.2.0 CT Models	Structure	Relevant FOV	Whole Body CT
	GlnD_Submand_L	*	95
	GlnD_Submand_R	*	100
	GlnD_Thyroid	*	82
	Kidney_L	*	91
	Kidney_R	*	95
	Liver	*	100
	Lung_L	*	100
	Lung_R	*	100
	Parotid_L	*	100
	Parotid_R	*	100
	Spleen	*	100

Percentage of images that were successfully localized by Contour ProtégéAI.

** The relevant FOV for the “SurePlan MRT” model is the Whole Body, so a separate “Relevant FOV” test was not performed.*

Each individual feature met the acceptance criteria defined for the verification and validation tests, and the entire software product was determined to be safe and effective for clinical use.

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.

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 this is unusually intense brain or kidney enhancement, the posterior boundary can be incorrectly segmented. The age breakdown of the training data, where patient age was available, was predominantly in the 40-60 and 60+ ranges. While this is appropriate to the intended patient populations,

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

Contour ProtégéAI+ has been developed according to MIM Software Inc.'s established design control process and software development life cycle. This includes risk management alongside verification and validation testing that includes testing of risk mitigations. Therefore, from all evidence gathered, it is MIM Software Inc.'s belief that Contour ProtégéAI+ (K250035) provides a device substantially equivalent to the predicate device.