March 27, 2026

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

Re: K253270
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: February 20, 2026
Received: February 20, 2026

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253270

Please provide the device trade name(s).

Contour ProtégéAI+

Please provide your Indications for Use below.

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, aiding image registration, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

• Segmenting structures across a variety of CT and MR anatomical locations.

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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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510(k) Summary

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

Submitter

MIM Software Inc.
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Cleveland, OH 44122

Phone:	216-455-0600
Fax:	216-455-0601
Contact Person:	Sydney Lindner
Date Summary Prepared:	March 24, 2026

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

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Predicate and Reference Devices

Predicate:	K250035	Contour ProtégéAI+	MIM Software Inc.
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. It includes processing components to allow the contouring of structures 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, aiding image registration, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

- Segmenting structures across a variety of CT and MR anatomical locations.

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.

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Compared to the predicate device, the intended use and indications for use for the subject device include minor modifications to improve clarity and completeness.

The upcoming 2.0.0 release of Contour ProtégéAI+ serving as the subject device in this 510(k) submission includes one new 4.3.0 neural network model (MR Brain) using the existing architecture cleared by the predicates, as well as one 5.0.0 neural network model (CT Male Pelvis) using the new architecture to allow the training of smaller networks for individual structures or groups of adjacent structures.

This 510(k) submission also includes plans for further development activities to Contour ProtégéAI+. Proposed modifications in the PCCP are categorized as follows:

- New CT models or MR models
- New CBCT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony Pro systems
- Re-training models due to improvements in training data
- Re-training models on cleared architecture
- Re-applying CT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony Pro systems

More details are provided in the **Predetermined Change Control Plan (PCCP)** section (pages 13-16).

Substantial Equivalence Discussion

The following table provides a comparison between the primary features of the subject device and its predicate, Contour ProtégéAI+ (K250035).

Table 1 – Comparison to predicate device

ITEM	Subject Device **Contour ProtégéAI+** MIM Software Inc. (K253270)	Predicate Device **Contour ProtégéAI+** MIM Software Inc. (K250035)	**Substantial Equivalence Discussion**
Clearance Date	TBD	February 3, 2025	N/A
Operating Platform	Server-based application supporting: • Linux-based OS • Local deployment on	Server-based application supporting: • Linux-based OS • Local deployment on	No change

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ITEM	Subject Device **Contour ProtégéAI+** MIM Software Inc. (K253270)	Predicate Device **Contour ProtégéAI+** MIM Software Inc. (K250035)	**Substantial Equivalence Discussion**
	Windows or Mac	Windows or Mac	
Modalities	CT and MR	CT and MR	No change
Atlas-based Segmentation	No	No	No change
Automatic contouring of 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 Network Architecture	Two different configurations of neural network architectures are used for training the 4.3.0 MR Brain model (A) and the 5.0.0 CT Male Pelvis model (B): (A) A single 3D U-Net is trained to produce all of the contours for a given model with the entire input image as an input. (B) **Multiple 3D U-Net models are trained, with each tailored to a specific anatomical structure or groups of structures (complexes) within a model bundle.** Rather than relying on a single network, this modular, multi-stage architecture employs three distinct neural networks to progressively localize and segment the target regions.	A single 3D U-Net is trained to produce all of the contours for a given model with the entire input image as an input.	The network architecture used for the 4.3.0 model is identical to the network architecture used in the models from the predicate device. The proposed change is the addition of a new multi-stage segmentation framework consisting of three networks, each based on the same 3D U-Net architecture as the predicate device. The proposed new framework is intended to improve runtime performance without compromising accuracy. The new framework is tested according to the same procedures and acceptance criteria as the predicate to ensure safety and effectiveness.

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ITEM	Subject Device **Contour ProtégéAI+** MIM Software Inc. (K253270)	Predicate Device **Contour ProtégéAI+** MIM Software Inc. (K250035)	**Substantial Equivalence Discussion**
Neural Network Models	(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 • SurePlan MRT CT (4.1.0 models) • Head and Neck CT • Thorax CT • Whole Body – Physiological Uptake Organs CT (4.2.0 models) • Thorax CT • Abdomen CT • Female Pelvis CT • SurePlan MRT 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 (3.1.0 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 • SurePlan MRT CT (4.1.0 models) • Head and Neck CT • Thorax CT • Whole Body – Physiological • Uptake Organs CT (4.2.0 models) • Thorax CT • Abdomen CT • Female Pelvis CT • SurePlan MRT CT	The subject device contains one new neural network model (4.3.0) and one updated neural network model (5.0.0) compared to the predicate. As described in the “Neural Network Architecture” section above, the new 4.3.0 model is trained on the same architecture as the predicate without any changes, and the updated 5.0.0 model is trained on a new architecture. These 2 models are 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.

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ITEM	Subject Device **Contour ProtégéAI+** MIM Software Inc. (K253270)	Predicate Device **Contour ProtégéAI+** MIM Software Inc. (K250035)	**Substantial Equivalence Discussion**
	(4.3.0 model) **• Brain MR*** **(5.0.0 model)** **• Male Pelvis CT**** ** New model.* *** Updated model.*		
Predetermined Change Control Plan (PCCP)	As part of continuous product development, MIM Software anticipates specific changes to be made to the Contour ProtégéAI+ device. These changes will improve user experience, expand segmentation capabilities, and provide support for processing a variety of anatomical images while utilizing the framework included in the predicate and subject device. The following device modifications are proposed: • New CT models or MR models • New CBCT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony Pro systems • Re-training models due to improvements in training data • Re-training models on cleared architecture • Re-applying CT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony	None	The new models generated by these modifications will be tested according to similar procedures and acceptance criteria as the predicate. All testing not significantly affected by the nature of the proposed modifications will be performed according to the same procedures and acceptance criteria as the predicate. The verification testing that will be affected by the nature of the proposed modifications will continue to contain both an overlap-based metric of Dice and a boundary-based metric of MDA as recommended by Maier-Hein, et. al, and metrics will be calculated according to the same procedures as the predicate. The acceptance criteria will only be adjusted when there is a more recently released model with the structure to perform non-inferiority testing on, in which case the non-inferiority testing will be compared to the most recently released Contour

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ITEM	Subject Device **Contour ProtégéAI+** MIM Software Inc. (K253270)	Predicate Device **Contour ProtégéAI+** MIM Software Inc. (K250035)	**Substantial Equivalence Discussion**
	Pro systems Specific models and contours to be added in future versions of the subject device are outlined in the PCCP, along with the contouring guidance references. The verification testing strategy for the proposed modifications is tailored to the specific nature of the changes. A comparative analysis to evaluate the performance of the new or retrained model directly against the cleared predicate device will be utilized when appropriate, otherwise acceptance criteria will follow American Association of Physicists in Medicine (AAPM) recommendations and acceptance criteria used by the reference devices: Radformation Inc. AutoContour Model RADAC V4 (K242729) and GE HealthCare MR Contour DL (K242925). This methodology provides the most appropriate and robust means of verifying the performance of the modified device. All other testing and acceptance criteria will be performed according to the same procedures and acceptance criteria as the predicate.		ProtégéAI+ model with the structure. When there is no previously released Contour ProtégéAI+ model with the structure to appropriately compare against, the acceptance criteria will be aligned with recommendations by AAPM and the acceptance criteria used by the reference devices, Radformation Inc. AutoContour Model RADAC V4 (K242729) and GE HealthCare MR Contour DL (K242925), to most accurately evaluate the models. These changes do not raise new questions for safety and effectiveness.

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Testing and Performance Data

Changes within this submission compared to the predicate device, Contour ProtégéAI+ (K250035), include one new MR 4.3.0 MR neural network model and one updated CT 5.0.0 neural network model with 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 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 189 images gathered from 7 institutions.

The CT images for this training set were obtained from clinical treatment plans for patients prescribed external beam or molecular radiotherapy and were re-segmented by consultants (physicians and dosimetrists) specifically for this purpose.

The verification data used for testing is independent 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 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 five-point scale for each contour, with one indicating unusable, two indicating major edits are necessary, three indicating minor edits that can be made in less time than starting from scratch are necessary, four indicating minor edits are not necessary, and 5 indicating the contour can be used-as-is. 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 3 or higher, when measured on a five-point scale.

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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.

The reference standards used for Dice and MDA testing consisted of images obtained from clinical treatment plans for patients prescribed external beam or molecular radiotherapy in which the contour set followed one of the following preparation protocols:

- *Not be Re-segmented*: The segmentations from the original treatment plans will be used, unedited.
- *Re-segmented*: After segmentation by a dosimetrist, the typical image review and QA protocol prior to radiation therapy will be performed: each segmentation will be reviewed by a team of dosimetrists, and then separately reviewed by a radiation oncologist. Segmentations that failed review will be referred for re-contouring by a dosimetrist, and then re-reviewed.

Independence of test data from training data was ensured by tracking the images used for training and testing. Each image was only used in either the test set or the training set.

Across the 189 individual patient testing data images, sex distribution was as follows: 28.0% female, 46.8% male, and 25.4% unknown. Manufacturer representation included GE (46.6%), Siemens (36.0%), Phillips (4.8%), Accuray (5.8%), and TomoTherapy (6.9%). For age distribution, 6.9% were between 20-40 years, 17.5% between 40-60 years, 51.3% over 60 years, and 24.3% unknown. All testing data originated from the United States, with regional breakdown as follows: Midwest (18.5%), South (54.0%), West (12.7%), and Northeast (14.8%).

The 5.0.0 CT Male Pelvis model was evaluated across sex, age, scanner manufacturer, U.S. Region, and contrast patient subgroups. Similarly, the 4.3.0 MR Brain model was evaluated across sex, age, scanner manufacturer, and contrast; however, regional evaluation was not performed because the verification dataset originated from a single institution. Results for the 5.0.0 CT Male Pelvis model indicated a performance reduction on female patients. The 5.0.0 CT Male Pelvis model is not intended for use on the female

patient population; instead, the 4.2.0 CT Female Pelvis model should be used on female patients.

Images acquired with Phillips and GE scanners, images with contrast, and images sourced from U.S. West region indicated a minor performance reduction for the 5.0.0 CT Male Pelvis model. In addition, results for the 4.3.0 MR Brain model indicated a minor performance reduction on images without contrast. Despite these limitations, all structures with sample size ≥ 3 demonstrated clinical non-inferiority.

The mean and standard deviation Dice coefficients and MDA scores 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. Additionally, the upper 95th percentile confidence bound of the difference between Contour ProtégéAI+ segmentation mean MDA and the MIM atlas segmentation K071964 (reference predicate) mean MDA and lower 95th percentile confidence bound of the difference between Contour ProtégéAI+ segmentation mean Dice and the MIM atlas segmentation K071964 (reference predicate) mean Dice were calculated. Contour ProtégéAI+ results were equivalent or had better performance than the MIM Maestro atlas segmentation reference device. Dice equivalence is defined such that the lower 95th percentile confidence bound of the of the difference between Contour ProtégéAI+ segmentation mean DICE and the MIM atlas segmentation K071964 (reference predicate) mean DICE Contour ProtégéAI+ segmentation is greater than -0.1. MDA equivalence is defined such that the upper 95th percentile confidence bound of the difference between Contour ProtégéAI+ segmentation mean MDA and the MIM atlas segmentation K071964 (reference predicate) mean MDA Contour ProtégéAI+ segmentation is less than 2mm.

Results over the verification testing set compared to the reference device are presented below.

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

Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI+	MDA MIM Atlas	MDA Contour ProtégéAI+	External Evaluation Score
4.3.0 MR Brain	Brain	0.96 ± 0.02	0.97 ± 0.01 (0.00) *	1.55 ± 0.60	1.21 ± 0.57 (0.14) *	4.4
	Brainstem	0.88 ± 0.02	0.90 ± 0.02 (0.00) *	0.93 ± 0.27	0.78 ± 0.29 (0.08) *	3.8
	Cochlea_L	0.13 ± 0.15	0.20 ± 0.20 (-0.08) **	1.85 ± 0.67	1.55 ± 0.66 (0.42) *	4.75

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Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI+	MDA MIM Atlas	MDA Contour ProtégéAI+	External Evaluation Score
	Cochlea_R	0.17 ± 0.19	0.21 ± 0.21 (-0.12) **	1.68 ± 0.88	1.52 ± 0.58 (0.61) *	4.75
	Eye_L	0.87 ± 0.03	0.90 ± 0.04 (0.00) *	0.83 ± 0.24	0.61 ± 0.32 (0.01) *	4
	Eye_R	0.87 ± 0.04	0.89 ± 0.03 (-0.01) *	0.80 ± 0.27	0.65 ± 0.27 (0.07) *	4
	Glnd_Lacrimal_L	0.42 ± 0.19	0.52 ± 0.23 (-0.07) **	1.16 ± 0.42	0.88 ± 0.75 (0.25) *	4.2
	Glnd_Lacrimal_R	0.41 ± 0.18	0.48 ± 0.26 (-0.12) **	1.36 ± 0.56	1.0.1 ± 0.70 (0.19) *	4.2
	Hippocampus_L	0.30 ± 0.16	0.39 ± 0.14 (-0.03) **	2.63 ± 1.05	2.33 ± 0.74 (0.45) *	4.5
	Hippocampus_R	0.34 ± 0.14	0.44 ± 0.11 (0.00) *	2.38 ± 0.96	1.97 ± 0.67 (0.27) *	4.5
	Lens_L	0.50 ± 0.16	0.71 ± 0.21 (0.05) **	1.00 ± 0.87	0.60 ± 0.87 (0.31) *	3.4
	Lens_R	0.51 ± 0.16	0.71 ± 0.23 (0.00) **	0.88 ± 0.42	0.36 ± 0.21 (-0.23) *	3.4
	OpticChiasm	0.49 ± 0.13	0.62 ± 0.10 (-0.09) *	1.18 ± 0.81	0.85 ± 0.43 (0.29) *	2.6
	OpticNrv_L	0.47 ± 0.12	0.52 ± 0.16 (-0.03) *	1.40 ± 0.66	1.41 ± 0.70 (0.63) *	3.8
	OpticNrv_R	0.43 ± 0.14	0.56 ± 0.15 (0.03) **	1.36 ± 0.49	1.08 ± 0.66 (0.26) *	3.8
	Pituitary	0.50 ± 0.16	0.58 ± 0.14 (0.16) **	1.06 ± 0.40	0.80 ± 0.28 (0.03) *	3.8
	SpinalCord	0.67 ± 0.14	0.77 ± 0.12 (-0.01) *	0.80 ± 0.41	0.43 ± 0.19 (-0.10) *	4.4
5.0.0 CT	Bladder	0.38 ± 0.13	0.91 ± 0.12 (0.15) *	4.21 ± 3.02	0.95 ± 1.28 (-2.46) *	4

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Model	Structure	Dice MIM Atlas	Dice Contour ProtégéAI+	MDA MIM Atlas	MDA Contour ProtégéAI+	External Evaluation Score
Male Pelvis	Bowel	0.21 ± 0.17	0.43 ± 0.10 (-0.01) *	8.24 ± 4.42	4.41 ± 1.95 (-1.82) **	4
	Colon_Sigmoid	0.89 ± 0.09	0.58 ± 0.27 (0.26) *	12.72 ± 8.87	9.18 ± 12.61 (1.76) **	3.2
	Femur_Head_L	0.90 ± 0.08	0.91 ± 0.08 (-0.01) *	1.04 ± 1.74	0.57 ± 1.59 (0.20) *	4.33
	Femur_Head_R	0.63 ± 0.04	0.91 ± 0.07 (-0.02) *	0.90 ± 1.31	0.58 ± 1.37 (0.22) *	4.33
	LN_Iliac	0.50 ± 0.15	0.71 ± 0.03 (0.05) *	3.15 ± 0.53	2.06 ± 0.33 (-0.78) *	4.66
	PenileBulb	0.75 ± 0.12	0.55 ± 0.18 (-0.02) *	2.32 ± 0.99	1.84 ± 0.89 (-0.06) *	4.2
	Prostate	0.62 ± 0.20	0.85 ± 0.08 (0.06) *	2.74 ± 1.33	1.52 ± 0.80 (-0.72) *	3.66
	Rectum	0.87 ± 0.01	0.81 ± 0.14 (0.13) *	4.02 ± 3.41	1.44 ± 1.47 (-1.66) *	3.66
	Sacrum	0.49 ± 0.26	0.93 ± 0.00 (0.02) *	1.06 ± 0.19	0.55 ± 0.08 (-0.04) *	4
	SeminalVes	0.78 ± 0.09	0.75 ± 0.12 (0.16) **	3.46 ± 3.62	1.20 ± 0.81 (-0.81) *	3.66

Mean ± Std DICE (lower 95th percentile confidence bound of the difference between the Contour ProtégéAI+ segmentation mean DICE and the MIM Atlas segmentation mean DICE based on a normal distribution with unequal variances)

Mean ± Std MDA (upper 95th percentile confidence bound of the difference between the Contour ProtégéAI+ segmentation mean DICE and the MIM Atlas segmentation mean DICE based on a normal distribution with unequal variances)

** 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 or the average external evaluation score is NOT greater than or equal to 3.

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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** – 4.3.0 and 5.0.0 models cumulative APL*

Models	MIM Atlas	Contour ProtégéAI+
4.3.0 MR Brain	51.55 ± 92.24	36.87 ± 72.40 (3.63%) *
5.0.0 CT Male Pelvis	257.21 ± 311.02	165.44 ± 235.96 (-21.5%) *

Mean ± Std APL mm (upper 95th percentile confidence bound of the difference between the Contour ProtégéAI+ segmentation mean APL and the MIM Atlas segmentation mean APL based on a normal distribution with unequal variances expressed as a percentage of the MIM atlas segmentation mean APL)

** Non-inferiority demonstrated at α=0.05 significance level*

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.

Predetermined Change Control Plan (PCCP)

This submission includes a Predetermined Change Control Plan (PCCP) detailing the proposed device modifications. The PCCP outlines the nature of these planned changes and provides a modification protocol to guide the verification, validation, and implementation processes, ensuring the device continues to meet substantial equivalence. The planned modifications described in the PCCP are summarized in the table below. In alignment with the PCCP, the updated Contour ProtégéAI+ device will undergo appropriate testing before being released with new or updated models. The User Guides and White Papers will be updated to include the relevant test results when these modifications are implemented. Upon release of a version, customers will be notified via email and/or direct contact from a MIM Software employee that an update is available for installation. In this communication to existing users, the release notes will be included to share with the users the changes and cautions discovered to make an informed decision about installing the update.

Table 4 describes each of the proposed modifications and how it will be tested to ensure substantial equivalence of the device after the modification.

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Table 4 – Traceability of PCCP modifications and per-structure testing protocol

Modification		Description	Per-Structure Testing Method
#1	**New CT models or MR models**	The modification adds new models to K253270, providing a more comprehensive set of anatomical contours to support clinicians in creating contours	Only structures that pass two or more of the following three tests could be included in the final models: 1. MDA Metric Testing 2. Dice Metric Testing 3. User Beta Testing
#2	**New CBCT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony Pro systems**	The modification adds new CBCT models to K253270, providing anatomical contours to support clinicians in creating contour on IRIS imaging CBCT data	Only structures that pass two or more of the following three tests could be included in the final models: 1. MDA Metric Testing 2. Dice Metric Testing 3. User Beta Testing
#3	**Re-training models due to improvements in training data**	This modification includes routine improvements to the current device by utilizing higher-quality or more diverse ground truth training data to improve overall segmentation accuracy or improve performance on subgroups with challenging anatomy	Only structures that pass two or more of the following three tests could be included in the final models: 1. MDA Metric Testing **AND** MDA Non-inferiority Testing with Contour ProtégéAI+ 2. Dice Metric Testing **AND** Dice Non-inferiority Testing with Contour ProtégéAI+ 3. User Beta Testing
#4	**Re-training models on cleared architecture**	This modification includes routine improvements to the current device by re-training on previously cleared architectures to improve overall segmentation accuracy or improve performance on subgroups with challenging anatomy and/or decrease computational time	Only structures that pass two or more of the following three tests could be included in the final models: 1. MDA Metric Testing **AND** MDA Non-inferiority Testing with Contour ProtégéAI+ 2. Dice Metric Testing **AND** Dice Non-inferiority Testing with Contour ProtégéAI+ 3. User Beta Testing

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Modification		Description	Per-Structure Testing Method
#5	**Re-applying CT models for CBCT IRIS imaging data (cleared in K252188) acquired from Elekta's Evo, Versa HD, and Harmony Pro systems**	This modification entails releasing previously released CT models, that are retested and renamed to provide anatomical contours to support clinicians in creating contours on IRIS imaging CBCT data	Only structures that pass two or more of the following three tests could be included in the final models: 1. MDA Metric Testing **AND** MDA Non-inferiority Testing with Contour ProtégéAI+ 2. Dice Metric Testing **AND** Dice Non-inferiority Testing with Contour ProtégéAI+ 3. User Beta Testing

MDA metric testing will involve a statistical evaluation to confirm results fall below the 3mm acceptance threshold, incorporating a clinically acceptable margin of error. MDA non-inferiority testing with Contour ProtégéAI+ is intended to confirm statistical non-inferiority of MDA compared with the most recently released Contour ProtégéAI+ model with the structure.

Dice metric testing will involve a statistical evaluation to confirm results exceed the contour specific Dice acceptance threshold, incorporating a clinically acceptable margin of error. For previously released structures, this threshold will be based on historically published Contour ProtégéAI+ performance. For new structures, this threshold will depend on the structure's size categorization as defined in ***Table 5***.

Table 5 *– Contour size categorization and associate Dice acceptance criteria threshold*

Contour Size Classification	Dice Acceptance Criteria Threshold
Small	0.5
Medium	0.65
Large	0.8

Dice non-inferiority testing with Contour ProtégéAI+ is intended to confirm statistical non-inferiority of the Dice score compared with the most recently released Contour ProtégéAI+ model with the structure.

User Beta Testing will use the established acceptance criteria.

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In addition to the per-structure testing, clinical validation, and subgroup analyses, cumulative Added Path Length (APL) will be evaluated for every modification to ensure substantial equivalence of the device after the modification.

Clinical validation will be conducted in-house to qualitatively evaluate contours compared to detailed criteria based on established clinical guidelines. Subgroup analyses will also be utilized to verify that performance satisfies requirements for either statistical homogeneity or clinical non-inferiority across mandatory cohorts such as age ranges, gender, contrast usage, scanner hardware, and institutional demographics, as well as supplementary cohorts identified by specific retraining triggers or artifacts common to the treatment.

In addition, each model as a whole will be evaluated. In order to be included in the released product, the cumulative Added Path Length (APL) of the contours in the model will be evaluated relative to the ground-truth using the established acceptance criteria.

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.

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+ provides a device substantially equivalent to the predicate device.