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

February 3, 2022

Re: K213976
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: December 30, 2021
Received: January 5, 2022

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,

Julie M. Sullivan, Ph.D.
Assistant Director
Nuclear Medicine and Radiation Therapy Branch
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213976

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 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.

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.

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

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

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

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

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

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

510(k) Summary

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

K213976

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: Feb 1, 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:	Medical Image management and processing system

Predicate Device

K210632	Contour ProtégéAI	MIM Software Inc.

Reference Device

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 allow the contouring of anatomical 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, transferring contours to radiation

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

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 normal structures of the prostate, seminal vesicles, and 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 4061 CT images from 31 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 3.0.0 production models.

CT data used to train the final production of the 3.0.0 CT models

Institution	Country	# of images
Institution 1	USA	22
Institution 2	USA	157
Institution 3	USA	105
Institution 4	Australia	420
Institution 5	USA	67
Institution 6	USA	46
Institution 7	USA	83
Institution 8	USA	82
Institution 9	USA	89
Institution 10	USA	63
Institution 11	France	40
Institution 12	USA	116
Institution 13	Hong Kong	394
Institution 14	USA	73
Institution 15	USA	230

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

Institution	Country	# of images
Institution 16	USA	139
Institution 17	USA	15
Institution 18	USA	96
Institution 19	USA	103
Institution 20	USA	29
Institution 21	USA	325
Institution 22	USA	13
Institution 23	USA	54
Institution 24	USA	10
Institution 25	USA	284
Institution 26	USA	622
Institution 27	USA	152
Institution 28	USA	58
Institution 29	USA	66
Institution 30	USA	101
Institution 31	USA	7

Substantial Equivalence

ITEM	Contour ProtégéAI (K213976)	Contour ProtégéAI (K210632)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Clearance Dates	TBD	10/20/2021	9/26/2007
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.	Contour ProtégéAI is an accessory to MIM software used for the contouring of anatomical structures in imaging data using machine-learning-based algorithms automatically.	MIM 4.1 (SEASTAR) software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical

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

ITEM	Contour ProtégéAI (K213976)	Contour ProtégéAI (K210632)	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. Contour ProtégéAI is not intended to detect or contour lesions.	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.	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 therapy, transferring contours to radiation therapy treatment planning systems and archiving contours for

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

ITEM	Contour ProtégéAI (K213976)	Contour ProtégéAI (K210632)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
			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 normal structures of the prostate, seminal vesicles, and	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	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

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

ITEM	Contour ProtégéAI (K213976)	Contour ProtégéAI (K210632)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	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.	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.	diagnosis, treatment evaluation, and treatment planning. • Localization and definition of objects such as tumors and normal tissues in medical images. • Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.
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 (K213976)	Contour ProtégéAI (K210632)	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	No

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

ITEM	Contour ProtégéAI (K213976)	Contour ProtégéAI (K210632)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
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 *(which include:* *Spleen* *Pelvic Lymph Nodes* *Descending Aorta* *Bone)*	***(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	None

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

Discussion

Changes within this submission include new CT 3.0.0 neural network models with additional contours. These changes differ when comparing to Contour ProtégéAI 510(k)210632. Non-inferiority testing was used to compare the proposed Contour ProtégéAI device to Atlases created from the MIM Maestro reference device.

Testing and Performance Data

For the proposed Contour ProtégéAI device, the new 3.0.0 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 4,061 images gathered from 31 clinical sites, from Australia, France, Hong Kong, and the USA. Models were trained using images of adults at various ages. No ethnicities or genders were excluded from training, with the exception of the training pool for the prostate model, for which only subjects with male anatomy were used. The models were then evaluated on the test subjects from a pool of 739 independent images gathered from 12 institutions.

The ground-truth segmentations used for both training and validation were generated by a trained user (typically, a dosimetrist or radiologist) that are then reviewed and approved by a supervising physician (typically, a radiation oncologist or a radiologist) and sent back for re-segmentation and re-review as necessary. The Dice coefficient was then calculated for each structure, and aggregated over all patients. 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.

With the MIM Maestro atlas segmentation reference device, multiple Atlases were created over the test subjects. Each Atlas contained images of the same anatomical field of view from the same institution. Each structure appeared in one Atlas. For each patient in an Atlas, the Atlas was used to segment the structures in that patient. The test patient itself was excluded from this Atlas (leave-one-out analysis).

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:

Structure:	MIM Atlas	Contour ProtégéAI
A_Aorta_Desc	0.73 ± 0.15	0.78 ± 0.07 (0.68) *
Bladder	0.80 ± 0.12	0.94 ± 0.02 (0.86) *
Bone	0.80 ± 0.03	0.83 ± 0.05 (0.76) *
Bone_Mandible	0.79 ± 0.16	0.83 ± 0.04 (0.74) *

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

Structure:	MIM Atlas	Contour ProtégéAI
Bowel †	0.60 ± 0.13	0.75 ± 0.07 (0.68) *
Bowel_Large	0.15 ± 0.12	0.28 ± 0.20 (0.15) *
Bowel_Small	0.29 ± 0.17	0.42 ± 0.19 (0.29) *
BrachialPlex_L	0.32 ± 0.11	0.37 ± 0.13 (0.27) *
BrachialPlex_R	0.38 ± 0.13	0.41 ± 0.10 (0.31) *
Brain	0.97 ± 0.01	0.96 ± 0.01 (0.95) *
Brainstem	0.77 ± 0.12	0.76 ± 0.12 (0.68) *
Breast_L	0.81 ± 0.06	0.81 ± 0.06 (0.76) *
Breast_R	0.83 ± 0.06	0.83 ± 0.06 (0.77) *
Bronchus	0.57 ± 0.12	0.62 ± 0.11 (0.54) *
Carina	0.54 ± 0.18	0.64 ± 0.17 (0.52) *
CaudaEquina	0.74 ± 0.09	0.72 ± 0.06 (0.64) *
Cavity_Oral	0.79 ± 0.10	0.81 ± 0.11 (0.73) *
Cochlea_L	0.39 ± 0.15	0.41 ± 0.17 (0.30) *
Cochlea_R	0.43 ± 0.15	0.46 ± 0.17 (0.34) *
Colon_Sigmoid	0.08 ± 0.09	0.50 ± 0.19 (0.33) *
Esophagus	0.43 ± 0.17	0.56 ± 0.19 (0.47) *
Eye_L	0.83 ± 0.10	0.82 ± 0.06 (0.77) *
Eye_R	0.81 ± 0.13	0.78 ± 0.06 (0.71) *
Femur_Head_L	0.93 ± 0.04	0.90 ± 0.06 (0.86) *
Femur_Head_R	0.93 ± 0.03	0.93 ± 0.03 (0.91) *
Femur_L	0.96 ± 0.01	0.95 ± 0.01 (0.93) *
Femur_R	0.96 ± 0.02	0.94 ± 0.01 (0.91) *
Genitals	0.64 ± 0.11	0.68 ± 0.13 (0.53) *
Glnd_Lacrimal_L	0.29 ± 0.15	0.39 ± 0.20 (0.24) *
Glnd_Lacrimal_R	0.31 ± 0.15	0.38 ± 0.22 (0.23) *
Glnd_Submand_L	0.68 ± 0.10	0.78 ± 0.07 (0.71) *

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

Structure:	MIM Atlas	Contour ProtégéAI
Glnd_Submand_R	0.67 ± 0.11	0.76 ± 0.06 (0.69) *
Glnd_Thyroid	0.51 ± 0.14	0.57 ± 0.18 (0.44) *
GreatVes	0.75 ± 0.06	0.71 ± 0.08 (0.65) *
Heart	0.85 ± 0.08	0.89 ± 0.04 (0.86) *
Humerus_Head_L †	0.88 ± 0.07	0.91 ± 0.04 (0.87) *
Humerus_Head_R †	0.88 ± 0.09	0.91 ± 0.03 (0.85) *
Kidney_L	0.76 ± 0.14	0.91 ± 0.03 (0.83) *
Kidney_R	0.74 ± 0.18	0.89 ± 0.04 (0.80) *
Larynx	0.52 ± 0.15	0.57 ± 0.18 (0.44) *
Lens_L	0.30 ± 0.17	0.52 ± 0.10 (0.41) *
Lens_R	0.36 ± 0.14	0.65 ± 0.09 (0.56) *
Lips	0.39 ± 0.14	0.57 ± 0.18 (0.43) *
Liver	0.84 ± 0.12	0.93 ± 0.04 (0.87) *
LN_Pelvic	0.76 ± 0.03	0.80 ± 0.04 (0.77) *
Lung_L	0.94 ± 0.03	0.95 ± 0.02 (0.93) *
Lung_R	0.95 ± 0.02	0.95 ± 0.02 (0.94) *
Musc_Constrict	0.44 ± 0.12	0.50 ± 0.17 (0.38) *
OpticChiasm	0.34 ± 0.16	0.37 ± 0.17 (0.25) *
OpticNrv_L	0.46 ± 0.12	0.52 ± 0.10 (0.44) *
OpticNrv_R	0.50 ± 0.10	0.54 ± 0.09 (0.47) *
Parotid_L	0.68 ± 0.13	0.81 ± 0.04 (0.74) *
Parotid_R	0.71 ± 0.10	0.78 ± 0.05 (0.72) *
PenileBulb	0.62 ± 0.12	0.65 ± 0.11 (0.56) *
Pituitary	0.53 ± 0.15	0.56 ± 0.18 (0.43) *
Prostate	0.71 ± 0.12	0.82 ± 0.06 (0.74) *
Rectum	0.67 ± 0.14	0.76 ± 0.08 (0.67) *
SeminalVes	0.58 ± 0.15	0.70 ± 0.08 (0.60) *

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

Structure:	MIM Atlas	Contour ProtégéAI
Spinal_Cord	0.76 ± 0.10	0.82 ± 0.07 (0.78) *
Spleen	0.78 ± 0.14	0.91 ± 0.07 (0.80) *
Stomach	0.45 ± 0.20	0.79 ± 0.09 (0.69) *
Trachea	0.77 ± 0.09	0.73 ± 0.07 (0.67) *

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.

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 K210632. In addition, the proposed device performs as well as the reference device, MIM 4.1 SEASTAR K071964.