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

October 20, 2021

Re: K210632
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: September 17, 2021
Received: September 20, 2021

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,

for
Thalia T. Mills, Ph.D.
Director
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)*
K210632

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.

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510(k) Summary

K210632

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

Submitter:

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

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

Contact Person: Lynn Hanigan

Date Summary Prepared: October 12, 2021

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

K193252	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.

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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 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.

Substantial Equivalence

ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Clearance Dates	TBD	7/2/2020	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. Appropriate image visualization software must be used to review and, if	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 must be used in conjunction with MIM software to	MIM 4.1 (SEASTAR) software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists.

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ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	necessary, edit results automatically generated by Contour ProtégéAI. Contour ProtégéAI is not intended to detect or contour lesions.	review and, if necessary, edit results automatically generated by Contour ProtégéAI. Contour ProtégéAI is not intended to detect or contour lesions automatically.	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 patient follow-up and management.

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ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
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 urethra within T2-weighted MR images. Appropriate image visualization software must be used to review and, if necessary, edit results	Contour ProtégéAI is used by trained medical professionals as a tool to aid in the automated processing of digital medical images of modalities CT and MR, as supported by ACR/NEMA DICOM 3.0. Contour ProtégéAI assists in the following indications: • The 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. Contour ProtégéAI must be used in conjunction with MIM software to review and, if necessary, edit contours that were	MIM 4.1 (SEASTAR) software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include, but are not limited to, CT, MRI, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 4.1 (SEASTAR) assists in the following indications: • Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects. • Create, display and print reports from medical images. • Registration, fusion display, and review of medical images for diagnosis, treatment 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

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ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
	automatically generated by Contour ProtégéAI.	automatically generated by Contour ProtégéAI.	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, MRI, CR, DX, MG, US, SPECT, PET and XA
Atlas-Based Segmentation	No	No	Yes
Automatically Contour Imaging Data Using Machine-Learning	Yes	Yes	No

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ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	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	***(1.0.0 models)*** Head and Neck CT Prostate CT Thorax CT Liver CT Prostate MR	None
Operating Platform	Server-based application supporting Linux-based OS - and - Local deployment on Windows or Mac	Server-based application supporting Linux-based OS	Windows, Mac
Cloud-based deployment	Yes	Yes	No

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ITEM	Contour ProtégéAI	Contour ProtégéAI (K193252)	MIM 4.1 SEASTAR [i.e., MIM Maestro] (K071964)
Locally deployed (or installed)	Yes	No	Yes

Discussion

Changes within this submission include a slightly modified Intended Use and Indications for Use, new and modified CT neural network models with additional contours, a modified Prostate MR neural network model, and added functionality to install locally on a MIM workstation or server. These changes differ when comparing to Contour ProtégéAI 510(k)193252. 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, neural network models were trained for each modality (CT and MR) on a pool of training data that did not include any patients from the same institution as the test subjects. The models were then evaluated on the test subjects, and a Dice coefficient was calculated for each structure. These Dice coefficients were then aggregated, overall patients.

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 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 Maestro atlas segmentation reference device performance.

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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(k)193252. In addition, the proposed device performs as well as the reference device, MIM 4.1 SEASTAR (k)071964 [MIM Maestro].