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

Re: K193252
Trade/Device Name: Contour ProtégéAI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QKB
Dated: June 1, 2020
Received: June 3, 2020

Dear Ms. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193252

Device Name
Contour ProtégéAI

Indications for Use *(Describe)*
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 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 of Safety and Effectiveness K193252
(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: 06/23/2020

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 Devices

K190379	MIM on Linux	MIM Software Inc.
K181572	Workflow Box	Mirada Medical Ltd.

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 must be used in conjunction with MIM software to review and, if necessary, edit results automatically generated by Contour ProtégéAI.

Contour ProtégéAI is not intended to detect or contour lesions automatically.

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

Indications for Use

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 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.

Substantial Equivalence

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
Clearance Date	TBD	03-19-2019	07-10-2018
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.	MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists.	Workflow Box is a system designed to allow users to route DICOM-compliant data to and from automated processing components. Workflow Box includes processing components for automatically contouring imaging data using deformable

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

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
	Contour ProtégéAI must be used in conjunction with MIM software to review and, if necessary, edit results automatically generated by Contour ProtégéAI. Contour ProtégéAI is not intended to detect or contour lesions automatically.	MIM 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 provides the user with the means to display, register and fuse medical images from multiple modalities. Additionally, it evaluates cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. The Region of Interest (ROI) feature reduces the time necessary for the user to define objects in medical image volumes by providing an initial definition of object contours. The objects include, but are not limited to, tumors and normal tissues. MIM 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	image registration and machine learning based algorithms. Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications. Workflow Box is not intended to automatically detect lesions.

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

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
		patient follow-up and management. MIM aids in the assessment of PET/SPECT brain scans. It provides automated quantitative and statistical analysis by automatically registering PET/SPECT brain scans to a standard template and comparing intensity values to a reference database or to other PET/SPECT scans on a voxel by voxel basis, within stereotactic surface projections or standardized regions of interest. MIM allows the dose distribution of an implant to be individually shaped for each patient and is a general-purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy using permanent implants of various radioisotopes (not including radioactive microspheres). MIM allows voxel-based dose calculations for patients who have been administered radioisotopes or radioactive microspheres.	
Indications for Use	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.	MIM 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,	Workflow Box is a software system designed to allow users to route DICOM-compliant data to and from automated processing components. Supported modalities include CT, MR, RTSTRUCT.

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

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
	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 automatically generated by Contour ProtégéAI.	SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM 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. • Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. • 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. • Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.	Workflow Box includes processing components for automatically contouring imaging data using deformable image registration to support atlas-based contouring, re-contouring of the same patient and machine learning based contouring. Workflow Box is a data routing and image processing tool which automatically applies contours to data which is sent to one or more of the included image processing workflows. Contours generated by Workflow Box may be used as an input to clinical workflows including, but not limited to, radiation therapy treatment planning. Workflow Box must be used in conjunction with appropriate software to review and edit results generated automatically by Workflow Box components, for example image visualization software must be used to facilitate the review and edit of contours generated by Workflow Box component applications. Workflow Box is intended to be used by trained medical professionals. Workflow Box is not intended to automatically detect lesions.

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

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
		• Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres). • Calculating absorbed radiation dose as a result of administering a radionuclide. When using device clinically, the user should only use FDA approved radiopharmaceuticals. If using with unapproved ones, this device should only be used for research purposes. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Images that are printed to film must be printed using an FDA-approved printer for the diagnosis of digital mammography images. Mammographic images must be viewed on a display system that has been cleared by the FDA for the diagnosis of digital mammography images. The software is not to be used for mammography CAD.	
Modalities	CT and MR	CT, MR, CR, DX, MG, US, NM, PET, XA, and other DICOM modalities	CT and MR

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

ITEM	MIM Software Inc. Contour ProtégéAI (K193252)	MIM Software Inc. MIM on Linux (K190379)	Mirada Medical Ltd. Workflow Box (K181572)
Atlas-based Contour Segmentation	No	Yes	Yes
Automatically Contour Imaging Data Using Machine-Learning	Yes	No	Yes
Operating Platform	Server-based application supporting Linux-based OS	Microsoft® Windows, Apple® OS, Linux-based OS	Server based application supporting Microsoft Windows 10 (64-bit) and Microsoft Windows Server 2016

Contour ProtégéAI is substantially equivalent to a combination of the predicate devices MIM on Linux (K190379) and Mirada Workflow Box (K181572).

Testing and Performance Data

The neural networks used in the Contour ProtégéAI device were trained on datasets from several large institutions. These datasets included CT images and MR images and their associated segmentations.

For testing, 286 images were used to evaluate the neural network models that segmented CT images, while 72 images were used to evaluate for the MR segmentation network. In all cases, the test images were gathered from a different and disjoint set of institutions from the training data. Both Contour ProtégéAI and the MIM predicate device were used to automatically segmented the independent test sets to show substantial equivalence.

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

To establish the performance of Contour ProtégéAI, a non-inferiority test was performed. This non-inferiority test compared the mean Dice coefficient of the automatically generated contours for Contour ProtégéAI against that of the predicate device. For all neural network models, evidence was established that the Contour ProtégéAI device was non-inferior to the predicate by at least a non-inferiority limit of 0.1 Dice, which was as the largest difference that is clinically acceptable based on previous studies, and thus we conclude that equivalence has been demonstrated.