MIM Software, Inc.
% Daniel Darkow
Clinical Science Team Lead
25800 Science Park Drive - Suite 180
CLEVELAND OH 44122

October 7, 2022

Re: K220256
Trade/Device Name: MIM-Ablation
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QTZ, LLZ
Dated: September 2, 2022
Received: September 6, 2022

Dear Daniel Darkow:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K220256

Device Name
MIM - Ablation

Indications for Use *(Describe)*
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, 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.

• Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).

• Calculating absorbed radiation dose as a result of administering a radionuclide.

• Assist with the planning and evaluation of ablation procedures by providing visualization and analysis, including energy zone visualization through the placement of virtual ablation devices validated for inclusion in MIM-Ablation. The software is not intended to predict specific ablation zone volumes or predict ablation success.

When using device clinically, within the United States, 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 a 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

Submitter:

MIM Software Inc.
25800 Science Park Drive – Suite 180
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Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Daniel Darkow

Date Summary Prepared: 10/04/2022

Device Name

510(k) Number:	K220256
Trade Name:	MIM – *Ablation*
Common Name:	Medical Imaging Software
Primary Regulation Number/Product Code:	21 CFR 892.2050 Product Code QTZ
Primary Classification Name:	Radiological Image Processing Software for Ablation Therapy Planning and Evaluation
Secondary Regulation Number / Product Code:	21 CFR 892.2050 Product Code LLZ
Secondary Classification Name:	System, Imaging Processing, Radiological

Predicate Devices

Primary:

K190379	MIM on Linux	MIM Software Inc.

Secondaries:

K202297	Aline Ablation Intelligence	Mirada Medical Ltd.

Intended Use

MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists.

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

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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 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.

MIM assists with the planning and evaluation of ablation procedures by allowing the energy zone that comprises the ablation zone to be visualized on medical imaging through the placement of virtual ablation devices for the purpose of confirming ablation zone placement.

Indications For Use

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, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

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• 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.

• Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).

• Calculating absorbed radiation dose as a result of administering a radionuclide.

• Assist with the planning and evaluation of ablation procedures by providing visualization and analysis, including energy zone visualization through the placement of virtual ablation devices validated for inclusion in MIM-Ablation. The software is not intended to predict specific ablation zone volumes or predict ablation success.

When using device clinically, within the United States, 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.

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
Clearance Date	TBD	03-19-2019	09-11-2020
Intended Use	MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists. 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	MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists and physicists. 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	Not listed

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
	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 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	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 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	

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
	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. MIM assists with the planning and evaluation of ablation procedures by allowing the energy zone that comprises the ablation zone to be visualized on medical imaging through the placement of virtual	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.	

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
	ablation devices for the purpose of confirming ablation zone placement.		
Indications for Use	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, MR, CR, DX, MG, US, 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.	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, 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.	Aline Ablation Intelligence is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures. Aline Ablation Intelligence is controlled by the user via a user interface on a workstation. Aline Ablation Intelligence imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures. Aline Ablation Intelligence is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. Aline Ablation Intelligence is used to assist physicians in confirming ablation zones. The software is not intended for diagnosis.

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
	• 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. • Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres). • Calculating absorbed radiation dose as a result of administering a radionuclide. • Assist with the planning and evaluation of ablation procedures by providing visualization and analysis, including energy zone visualization through the placement of virtual ablation devices validated for inclusion in MIM-	• 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. • Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres). • Calculating absorbed radiation dose as a result of administering a radionuclide.	The software is not intended to predict ablation volumes or predict ablation success.

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
	Ablation. The software is not intended to predict specific ablation zone volumes or predict ablation success. When using the device clinically, within the United States, 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 a 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.	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.	

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
Operating Platform	Microsoft Windows, Apple® OS X	Microsoft Windows, Apple® OS X	Unknown
Receive, transmit, display and general manipulation (window/level, pan, zoon, cross-hairs, slice navigation) of medical images	Yes	Yes	Yes
Supported Imaging Modalities	CT, MR, CR, DX, MG, US, NM, PET, XA, and other DICOM modalities	CT, MR, CR, DX, MG, US, NM, PET, XA, and other DICOM modalities	CT and MR
Image Segmentation	Tools for segmenting 3D structures, including normal structures, lesions, and ablation zones. (This functionality is unchanged from MIM on Linux)	Tools for segmenting 3D structures, including normal structures, and lesions.	Tools for segmenting 3D VOIs, including target tissues and ablation zones.

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
Derive volume statistics from segmentations	Yes (This functionality is unchanged from MIM on Linux)	Yes	Yes
Automated ablation margin creation through the expansion of a designated segmentation	Yes (This functionality is unchanged from MIM on Linux)	Yes	Yes
Image re-slicing orthogonally to a user-defined angle to give a "probe's-eye view" image for planning	Yes (This functionality is unchanged from MIM-Brachy (K103576) which is a precursor 510(k) to MIM on Linux)	Yes	No

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ITEM	MIM – *Ablation* (K220256)	MIM on Linux (K190379)	Mirada Aline Ablation Intelligence (K202297)
Placement of pre-defined energy zone volumes per specified grid locations on a medical image	Yes	No	Yes
Registration of planning imaging to in-procedure and/or post-ablation imaging for the purpose of ablation zone confirmation	Yes (Image registration functionality is unchanged from MIM on Linux)	Yes	Yes

Device Description

MIM - Ablation is a standalone software application that allows for the planning and evaluation of ablation procedures. This is achieved by utilizing the following functionality:

- Manual and automatic tools for normal structure, target region, and ablation zone segmentation
- Image re-slicing and reorientation orthogonally to a user-defined angle to give a "probe's-eye view" image for planning
- Manual and constraint-driven placement of virtual ablation devices on medical imaging in order to visualize the ablation energy zones.
- The calculation of the percentage of designated structures that are covered by each energy zone during planning, as well as a calculation of the final ablation zone coverage after the ablation has been performed

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- Multimodality image registration, including rigid and deformable fusion, for the comparison of images taken at different times during the ablation planning and treatment administration

MIM – Ablation is run on a dedicated workstation in the hospital healthcare environment and can be used with an 3D DICOM image. The software can be used on image data for any patient demographic that is undergoing ablation treatment with devices validated for inclusion in MIM - Ablation.

Substantial Equivalence

MIM – *Ablation* is substantially equivalent to a combination of the primary predicate device MIM on Linux (K190379) and Aline Ablation Intelligence (K202297).

Testing and Performance Data

MIM Software Inc. has conducted performance and integration testing on MIM - *Ablation* software that fully evaluated all the functions. The data support verification in energy zone dimensions, image resolution independence, contour resolution independence, image modality independence, percent coverage of regions, HIFU energy zone dimensions, and constraint driven planning. The verification and validation testing follow 21 CFR part 820.30 and satisfies the FDA “Guidance on Software Contained in Medical Devices” requirements. Potential risks were mitigated and reflected in the device labeling and design.

The ablation devices that were included in the verification and validation of MIM-Ablation are the Varian V-Probes (part of the CryoCare Touch System, K201588) and the SonaBlate HIFU system (K160942). The specific energy zone characteristics that were used to generate models and import into MIM-Ablation were taken from user guides and marketing material for each ablation device.

The dimensions of the energy zones that are imported as 3D objects in MIM match the dimensions for that energy zone as specified by the ablation device manufacturer. The measurements of the initial 3D models of the energy zones in the CAD (computer-aided design) software and the MIM contour measurements fell within the range of the manufacturer tolerance. In addition, the CAD measurement had a range of -3.75% to 1.53% percent difference compared to MIM contour measurements.

The volume of the energy zones that are imported as 3D objects in MIM are independent of image resolution. This work compared expected volumes to MIM volume at 0.5 mm, 1.0 mm, and 1.5 mm image resolutions to verify consistency. Percent difference ranged from -1.65 % to 0.29%. at 0.5 mm, -0.87% to -0.6% at 1.0 mm, and -0.70% to 0.00% at 1.5 mm image resolution.

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The dimensions of the energy zones that are imported as 3D objects in MIM match the dimensions for that energy zone as specified by the ablation device manufacturer independent of contour resolution. Percent difference ranged from -1.43% to -0.43% at 0.25 mm, -1.16% to 0.00% at 0.5 mm, and -2.15% to -0.38% at 1.0 mm contour resolution.

The dimensions of the energy zones as 3D objects in MIM match the dimensions of the energy zone as specified by the ablation device manufacturer across four image modalities. Percent difference ranged from 0.64% - 0.89%. This highlights the minimal effect image modality has on contour dimensions.

MIM provides the statistic “Percent Coverage” that indicates the volume of the structure being covered by the volume of the energy zone. The percent coverage statistic with one or multiple ablation probes placed on an image was verified. Percent difference ranged from 0.00% to 1.57%. with one ablation probe and 0.00% to 0.19% with two ablation probes.

The dimensions of the unique energy zone, HIFU, are generated as specified by the ablation probe manufacturer. The 3cm transducer treatment zone height, 4cm transducer treatment zone height, and overlap were measured in MIM and in Sonablate to verify that they matched the manufacturer’s dimensions. Percent error ranged from 0.00% to 6.00%. These measurements fell within the range of the manufacturer tolerance. This work verified the consistency in HIFU dimensions compared to the manufacturer’s measurements.

This work verified that the constraint-driven planning functionality places energy zones that adhere to the constraints as set by the user. These constraints ensure ablation probes target the appropriate region of interest. In addition, this work verified that an unattainable plan occurs when the scenario is not possible.

Conclusion

Based on the Device Description and Testing and Performance Data above, the proposed device is determined to be as safe and effective as the predicate devices MIM on Linux (K190379) and Aline Ablation Intelligence (K202297).