



May 13, 2024

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

Re: K232862

Trade/Device Name: MIM - Monte Carlo Dosimetry
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 9, 2024
Received: April 9, 2024

Dear Sydney Lindner:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K232862

Device Name

MIM - Monte Carlo Dosimetry

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, 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.
- 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 the device clinically, within the United States, the user should only use FDA approved radiopharmaceuticals. If used 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.

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.



510(k) Summary of Safety and Effectiveness
(The following information is in conformance with 21 CFR 807.92)

Submitter

K232862

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

Phone: 216-455-0600

Fax: 216-455-0601

Contact Person: Sydney Lindner

Date Summary Prepared: April 9, 2024

Device Name

Trade Name: MIM – *Monte Carlo Dosimetry*
(K232862)

Common Name: Medical Imaging Software

Regulation Number / Product Code: 21 CFR 892.2050 Product Code LLZ

Classification Name: System, Imaging Processing,
Radiological

Predicate Devices

Primary: K220256 MIM – *Ablation* MIM Software Inc.

Reference: K033960 OLINDA/EXM Vanderbilt University

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, MR, 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, 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.
- 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 the device clinically, within the United States, the user should only use FDA approved radiopharmaceuticals. If used 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.

Device Description

MIM – *Monte Carlo Dosimetry* (K232862) extends the features of MIM – *Ablation* (K220256). It is designed for use in medical imaging and operates on Windows, Mac, and Linux computer systems. The intended use and indications for use in MIM – *Monte Carlo Dosimetry* are unchanged from the predicate device, MIM – *Ablation* (K220256).

MIM – *Monte Carlo Dosimetry* (K232862) is a standalone software application that extends the functionality of the predicate device by providing:

- Dose calculation of radionuclides performed using a Monte Carlo method

Substantial Equivalence

MIM – *Monte Carlo Dosimetry* is substantially equivalent to the predicate devices, MIM – *Ablation* (K220256) and OLINDA/EXM (K033960).

ITEM	Subject Device: MIM – <i>Monte Carlo Dosimetry</i> (K232862)	Predicate Device: MIM – <i>Ablation</i> (K220256)	Reference Predicate: OLINDA/EXM (K033960)
Clearance Date	TBD	October 7, 2022	June 15, 2004
Intended Use	<p>MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists.</p> <p>MIM is a medical image and information management system that is intended to receive, transmit, store,</p>	<p>MIM software is intended for trained medical professionals including, but not limited to, radiologists, oncologists, physicians, medical technologists, dosimetrists, and physicists.</p> <p>MIM is a medical image and information management system that is intended to receive, transmit, store,</p>	<p>The purpose of OLINDA/EXM is to estimate radiation doses received by internal organs as a result of administering a radiopharmaceutical.</p>

	<p>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, MR, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	
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	<p>database or to other PET/SPECT scans on a voxel-by-voxel basis, within stereotactic surface projections or standardized regions of interest.</p> <p>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).</p> <p>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.</p>	<p>database or to other PET/SPECT scans on a voxel-by-voxel basis, within stereotactic surface projections or standardized regions of interest.</p> <p>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).</p> <p>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.</p>	
Indications for Use	<p>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:</p> <ul style="list-style-type: none"> • Receive, transmit, store, retrieve, display, print, and 	<p>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:</p> <ul style="list-style-type: none"> • Receive, transmit, store, retrieve, display, print, and 	<p>Estimates the absorbed doses to several tissues of a reference patient for a specified radiopharmaceutical dosage.</p>

	<p>process medical images and DICOM objects.</p> <ul style="list-style-type: none"> • 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 	<p>process medical images and DICOM objects.</p> <ul style="list-style-type: none"> • 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 	
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	<p>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.</p> <p>When using the device clinically, within the United States, the user should only use FDA approved radiopharmaceuticals. If used with unapproved ones, this device should only be used for research purposes.</p> <p>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.</p>	<p>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.</p> <p>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.</p> <p>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.</p>	
Operating Platform	Microsoft Windows, Apple® OS X, Linux-based OS	Microsoft Windows, Apple® OS X, Linux-based OS	Microsoft Windows
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	None
Receive, transmit, display, general manipulation (window/level, pan, zoom, cross-hairs, slice navigation), and co-registration of medical images	Yes	Yes	No
3D image	Yes	Yes	No

segmentation			
Dose calculation of radionuclides from activity images	LDM, Monte Carlo derived VSV, and full Monte Carlo	LDM and Monte Carlo derived VSV	Model-based with Monte Carlo derived S-values

Testing and Performance Data

Software verification and validation testing included 4 main sections: 1) Comparison to model-based dose calculation with Monte Carlo derived S-values, 2) Comparison to voxel-based dose calculation with Monte Carlo derived voxel S-value (VSV), 3) Comparison to a well-established Monte Carlo dose calculation algorithm, 4) Characterization of user inputs for number of simulated particle histories, number of computational threads, and the simulation starting point.

MIM – *Monte Carlo Dosimetry* was compared to model-based dosimetry with Monte Carlo derived S-values in OLINDA/EXM (K033960) for Lu-177, I-131, and Y-90 activity maps. A testing dataset was created from an existing CT scan of the patient that was of height (1.7m) and weight (77kg) similar to the default Adult Male model in OLINDA (1.7m, 70kg). Each region was masked to a realistic relative activity per isotope with the rest-of-body region normalized to 1. Mean absorbed doses were compared for kidneys, spleen, lungs, liver, salivary glands, lacrimal glands, thyroid and tumors. For all structures and isotopes, the average, absolute percent difference between the dose calculation methods was 4.3%. The differences observed between MIM - *Monte Carlo Dosimetry* and OLINDA is within the expected range based on a similar study¹ conducted with ¹⁷⁷Lu-DOTATATE data where the two methods differed by 5% on average.

There were high differences in lung dose at 18.1%, 31.2%, and 10.8% for Lu-177, I-131, and Y-90, respectively. Without those comparisons, the average difference drops to 2.5% across the other structures. The differences for Lu-177 and Y-90 lung dose can be attributed to the model-based dosimetry in OLINDA underestimating lung dose by not accounting for the cross-dose from the nearby tumors in the liver. The larger difference in lung dose for I-131 can be attributed to the greater amount of high energy photons in addition to differences in the OLINDA model and the patient-specific lung geometry (30% smaller) leading to the significantly higher amount of cross-dose from nearby high-activity structures to be underestimated.

Dose calculation in MIM – *Monte Carlo Dosimetry* was also compared to the predicate Voxel S-value (VSV) dose calculation in MIM – *Ablation* (K220256). The same patient data from the model-based dosimetry comparison was used for the VSV comparison.

For all structures and isotopes, the average, absolute percent difference was 6.0%. This difference between a VSV method and a Monte Carlo method is consistent with previously published² results for another commercial, voxel-based VSV software where organ dosimetry differed by ~10%.

The largest difference was seen for the lung dose using I-131 (61%). The average difference across all structures drops to 4.0% without the lung comparison for I-131. Larger differences in lung dose are expected when comparing Monte Carlo methods to VSV methods due to the overestimation of dose in structures significantly lower in density than the simulation material. The VSV kernel was generated assuming water density, thus, for energy deposited by beta and gamma particles in low density regions the VSV method overestimates dose as the particles travel further before being absorbed than they would in soft tissue. Whereas the Monte Carlo dose calculations account for density with the material simulation and more accurately estimate the deposited energy from beta and gamma particles in the low density tissue of the lungs. For I-131, there is a greater amount of high energy particles so the effect of nearby high-activity structures on the lung dose with the VSV approach is greater than Lu-177 or Y-90. This difference in lung dosimetry was expected and within the range of previously reported discrepancies in a study that investigated the effects of tissue inhomogeneities on the VSV method³, where lung dose differed by 30-60% when compared to Monte Carlo dosimetry.

Lastly, MIM – *Monte Carlo Dosimetry* was compared directly to a well-established Monte Carlo dose calculation algorithm, GATE (GEANT4 Application for Tomographic Emission). The same patient data from the model-based dosimetry comparison was used in this comparison. The two methods were in high agreement, with an average, absolute difference of 1.4% across all structures and isotopes. It was found that the Monte Carlo calculations differed by 2-3% for Lu-177, I-131, and Y-90.

Characterization of the user inputs to the simulation showed that the default setting for 1×10^8 particle histories is appropriate for accurate dose calculation and provided characterization for using more or less particles than the default. 1×10^8 particle histories results in less than 1% uncertainty in regions of interest and less than 1% difference between results when running multiple simulations with random simulation seeds.

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 – *Ablation* (K220256) and OLINDA/EXM (K033960).

References

1. Kim KM, Lee MS, Suh MS, et al. Comparison of voxel S -value methods for personalized voxel-based dosimetry of ^{177}Lu -DOTATATE. *Med Phys*. 2022;49(3):1888-1901. doi:10.1002/mp.15444
2. Stamouli I, Nanos T, Chatzipapas K, et al. Dosimetric Evaluation of ^{177}Lu Peptide Receptor Radionuclide Therapy Using GATE and Planet Dose. *Appl Sci*. 2023;13(17):9836. doi:10.3390/app13179836
3. Götz T, Schmidkonz C, Lang EW, Maier A, Kuwert T, Ritt P. A comparison of methods for adapting ^{177}Lu dose-voxel-kernels to tissue inhomogeneities. *Phys Med Biol*. 2019;64(24):245011. doi:10.1088/1361-6560/ab5b81