



December 18, 2018

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

Re: K182624
Trade/Device Name: MIM - MRT Dosimetry
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 21, 2018
Received: September 24, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Rob A. Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K182624

Device Name
MIM - MRT 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, 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.

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 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 of Safety and Effectiveness
(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: 09/21/2018

Device Name

Trade Name:	MIM – MRT Dosimetry
Common Name:	Medical Imaging Software
Regulation Number / Product Code:	21 CFR 892.2050 Product Code LLZ
Classification Name:	System, Imaging Processing, Radiological

Predicate Devices

K172218	MIM – Y90 Dosimetry	MIM Software Inc.
K180815	MIM – SPECTRA Quant	MIM Software Inc.
K163687	OLINDA/EXM 2.0	Hermes
K153355	Xeleris 4.0	GE Healthcare

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 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.

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:

- 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.



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Device Description

MIM - *MRT Dosimetry* extends features of MIM SurePlan. It is designed for use in medical imaging and operates on both Windows and Mac computer systems. MIM - *MRT Dosimetry* extends the functionality of the MIM - Y90 Dosimetry (K172218) software and utilizes functionality of MIM – SPECTRA Quant (K180815). Both of these are predicates for this submission. The following functions have been added to allow calculations of absorbed dose as a result of administering a radionuclide.

- Allows for quantification of planar images
- Allows for calculation of time-integrated activity coefficients
- Allows for voxel-based dose calculation of radionuclides
- Allows for correction of dose for tissue density

Substantial Equivalence

MIM – *MRT Dosimetry* is substantially equivalent to a combination of the predicate devices MIM – Y90 Dosimetry (K172218), MIM – SPECTRA Quant (K180815), OLINDA/EXM 2.0 (K163687), and Xeleris 4.0 (K153355).

Performance Data

MIM Software Inc. has conducted performance and integration testing on MIM - *MRT Dosimetry* software with a comparison to a commercially available solution for internal radionuclide dosimetry. Standard quality control phantoms, simulated phantoms based on the NEMA IEC Body Phantom, simulated phantoms based on patient data, and clinical patient data were used for verification testing. All tests were performed using standard clinical acquisition and reconstruction protocols.

The accuracy of planar corrections for attenuation, scatter, and background were verified in simulated phantoms. The average errors were less than 12% for all regions except for the smallest region (2.6 cm) with 21% error for Lu-177 and 17% error for I-131 where the partial volume effect lowered accuracy as expected. In all cases, the software passed its performance requirements and met specifications

The accuracy of area-under-the curve (AUC) calculations were verified for different fitting options using simulated data with differences less than 3.1% compared to manual AUC calculations which met predefined acceptance criteria when considering the presence of Poisson noise in the image data.



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The accuracy of the generation of CT-derived physical density maps were verified in clinical patient data and compared to published results with less than 5% difference for soft tissue regions and less than 10% difference for bone regions. The difference for lung density fell within the range of expected density values.

The accuracy dose calculations using MIM - MRT Dosimetry was verified in simulated phantoms and clinical patient data for I-131 and Lu-177. The acceptance criterion for MIM - MRT Dosimetry is a difference of mean dose of smaller or equal to 20% in comparison to a commercially available solution after correction of the standard phantoms in the commercial solution to match the mass of the patient data. Additionally, comparison of the Voxel S Value method in MIM - MRT Dosimetry to Local Deposition Model values for Lu-177 showed a difference less than 1% for all organs tested. In all cases the software demonstrated acceptable agreement between the different dose methods.

In conclusion, MIM Software Inc. has conducted performance testing on the MIM – MRT Dosimetry software. In all cases, the software passed its performance requirements and met specifications.