January 17, 2023

MIM Software Inc.
% Megan Fontanez
Clinical Science Team Lead
25800 Science Park Drive - Suite 180
CLEVELAND OH 44122

Re: K223800
Trade/Device Name: MIM - Additional Tracers
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 16, 2022
Received: December 19, 2022

Dear Megan Fontanez:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

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)*
K223800

Device Name
MIM - Additional Tracers

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 this 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 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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K223800

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: Megan Fontanez

Date Summary Prepared: December 16, 2022

Device Name

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

Predicate Device

K190379	MIM – *On Linux*	MIM Software Inc.

Reference Device

K060816	MIM 4.0 (NEURO)	MIMvista Corp.

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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:

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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.

When using this 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 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.

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Device Description

MIM - Additional Tracers is an expansion of the standalone software application MIM - On Linux (K190379). MIM - Additional Tracers Indications for Use have not been modified, and the Intended Use is the same as in MIM - On Linux. With the addition of additional tracers to the standalone MIM software, engineering drawings, schematics, etc. are not applicable to the device.

These Indications for Use include quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans. MIM - *Additional Tracers* includes the above features and capabilities and adds support for new PET/SPECT new tracers. While MIM - *On Linux* supported FDG and HMPAO tracers, this special 510k submission includes new tracers support for: Amyvid™ (Florbetapir), Vizamyl™ (Flutemetamol), Neuraceq™ (Florbetaben), and DaTscan™ (Ioflupane).

MIM - A*dditional Tracers* operates on Windows, Mac, and Linux computer systems.

Substantial Equivalence

ITEM	MIM – *ADDITIONAL TRACERS* (K# - TBD)	MIM ON LINUX (K190379)	MIM 4.0 NEURO (K060816)
Clearance Dates	TBD	March 19, 2019	March 24, 2006
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,	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,	MIM 4.0 (NEURO) is a software package that provides the physician 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 physician to define objects in medical

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ITEM	MIM – *ADDITIONAL TRACERS* (K# - TBD)	MIM ON LINUX (K190379)	MIM 4.0 NEURO (K060816)
	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	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	image volumes by providing an initial definition of object contours. The objects include but are not limited to tumors and organs. MIM 4.0 (NEURO) also aids the physician 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 within standardized regions of interest"

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ITEM	MIM – *ADDITIONAL TRACERS* (K# - TBD)	MIM ON LINUX (K190379)	MIM 4.0 NEURO (K060816)
	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.	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.	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.	The MIM software program should be used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIM assists in definition of structures in medical images including tumors, organs, and cardiac left ventricular cavity. MIM aids in the assessment of PET/SPECT brain scans by providing quantitative and statistical comparisons to other registered

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	• 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 this device clinically within the United	• 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	PET/SPECT brain scans.

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ITEM	MIM – *ADDITIONAL TRACERS* (K# - TBD)	MIM ON LINUX (K190379)	MIM 4.0 NEURO (K060816)
	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 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.	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.	
Receive, Transmit, Retrieve, Display, Print Digital Medical Images	Yes	Yes	Yes
MIM workstation features and functionality	Yes	Yes	Yes
Operating Platform	Microsoft Windows, Apple® OS Linux-based OS	Microsoft Windows, Apple® OS Linux-based OS	Microsoft Windows, Apple® OS
Tracer Support	PET • FDG • Amyvid™ (Florbetapir),	PET • FDG SPECT • HMPAO	PET • FDG SPECT • HMPAO

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	• Vizamyl™ (Flutemetamol), • Neuraceq™ (Florbetaben), SPECT • HMPAO • DaTscan™ (Ioflupane)		

Discussion

MIM – *Additional Tracers* is substantially equivalent to past MIM software 510(k) clearances. MIM – *on Linux* was chosen as the predicate device to represent the broad range of indications for use and intended uses that encompasses MIM software. The comparison chart above shows that the only difference within this catch-up special 510(k) is the additional tracer support.

Testing and Performance Data

Template registration accuracy for each tracer and corresponding clinical use case was assessed by a radiologist and MIM technical experts. Risk mitigation for automatic registration error is built-in to the software with registration adjustment and verification steps. For amyloid PET registration, the user inspects and adjusts affine registration to template space with displayed fusions to an amyloid positive, amyloid negative, and mean template. There is a secondary verification step to confirm registration accuracy as well. For DaTscan registration, there is built-in affine registration to the template and individual hemisphere verification and adjustment to ensure accurate placement of the reference and analysis regions.

Normal patient scans were curated to span demographics appropriate for each tracer. After selection, these series were then aligned to template space to create databases for each tracer. Alignment to template space and accuracy of analysis contours for each tracer were approved by a radiologist and MIM technical experts before each series could be included in the normals database.

Quantitative analysis results on a selection of scans representative of the population for each tracer were compared to expert reads and reviewed by physicians and MIM technical experts. Discrepancies were only acceptable for misregistered, borderline, or poor-quality scans.

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Conclusion

Based on the Discussion and Testing and Performance Data, the proposed device is determined to be as safe and effective as its predicate device, K190379 (MIM – On Linux), and its reference device, K060816 (MIM 4.0 Neuro).