December 11, 2025

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

Re: K251883
Trade/Device Name: MIM - LesionID Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 23, 2025
Received: October 23, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251883

Device Name
MIM – LesionID Pro

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, staging, treatment planning, monitoring treatment response, and treatment evaluation.

• 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.

When used for diagnostic purposes, the mobile thin client is not intended to replace a full workstation and should only be used when there is no access to a workstation.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K251883

510(K) SUMMARY

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date	June 18, 2025
Submitter	MIM Software Inc. 25800 Science Park Drive – Suite 180 Cleveland, OH 44122 Phone: 216-455-0600 Fax: 216-455-0601
Primary Contact	Sydney Lindner, Regulatory Affairs Engineer
Secondary Contact	George Mashour, Sr. Regulatory Affairs Manager, MI

Device Name

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

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Predicate Devices

Primary:	MIM – *Symphony HDR Fusion* MIM Software Inc. K243012 | October 23, 2024
Secondary:	PET VCAR GE Medical Systems SCS K211247 | July 27, 2021

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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 software can be used by clinicians to assist in diagnosis, staging, treatment planning, monitoring treatment response, and treatment evaluation.

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.

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Indications for Use

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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, staging, treatment planning, monitoring treatment response, and treatment evaluation.*
- *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.*

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Device Description

The subject MIM – *LesionID Pro* device is a standalone software application that extends the functionality of the MIM software device. It is a modification to the predicate MIM software application (K243012) for incorporating updates to the LesionID Pro option that is commercially available in the currently distributed version of MIM software.

LesionID Pro assists users with the evaluation of PSMA PET/CT and SPECT/CT studies by automating hotspot segmentation and physiological uptake removal, to help reduce manual processing and streamline generation of Total Tumor Burden (TTB) statistics. It is provided via MIM Workflows that allow automation using scripts constructed of MIM software modular functions and commands.

LesionID Pro does not determine final hotspots segmentation for TTB generation, and requires users to review, edit, and confirm the segmentation before generating TTB statistics. The modifications made to LesionID Pro optimize the identification and removal of physiological uptake, automates the processing for a more streamlines workflow, and introduced enhancements related to user interface and experience.

Comparison to Predicate Devices

The table below summarize the substantive feature / technological differences between the subject device and the primary predicate device and the subject device:

Table 1 *– Subject device comparison to predicate devices.*

ITEM	SUBJECT DEVICE: MIM Software Inc. MIM – *LesionID Pro*	PRIMARY PREDICATE DEVICE MIM Software Inc. MIM – *Symphony HDR Fusion* (K243012)	SECONDARY REFERENCE DEVICE: GE HealthCare PET VCAR (K211247)
Operating Platform	Microsoft Windows, Apple® OSX, Linux-based OS	Microsoft Windows, Apple® OSX, Linux-based OS	GE HealthCare Advantage Workstation OS
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	PET, CT
Fully automated workflow initialization using MIM Assistant	Yes	Yes	No

ITEM	SUBJECT DEVICE: MIM Software Inc. MIM – *LesionID Pro*	PRIMARY PREDICATE DEVICE MIM Software Inc. MIM – *Symphony HDR Fusion* (K243012)	SECONDARY REFERENCE DEVICE: GE HealthCare PET VCAR (K211247)
Automatic contouring of normal structures using MIM Software accessory, Contour ProtégéAI+	Yes Contour ProtégéAI+ (K250035)	Yes	No
Hotspot segmentation on functional DICOM images	Yes	Yes	Yes
Physiological uptake identification	Yes automated identification and removal, with user edits (as needed)	Yes manual identification and removal through user interactions	No
Reference region generation	Yes automated in the liver and mediastinum bloodpool ROIs with user edits (as needed)	Yes possible only through manual user interactions	Yes automated in the liver ROI with user edits as needed
Total tumor burden (TTB) ROI generation and quantification	Yes automated with user edits as needed	Yes possible only through manual user interactions	No

Determination of Substantial Equivalence

Non-Clinical - Software Verification and Validation Testing

Verification and validation tests have been completed for each design requirement to confirm that the specifications (outputs) meet the input requirements. The verification and validation tests include testing of functional (technical) requirements and user interface requirements against established acceptance criteria. These tests assessed LesionID Pro functionalities, including primary aspects as:

- LesionID Pro Targets (MIM Assistant and Manual Processing)

- Importing and Editing Processed Series
- Identification of Modality and Processing Logic
- Segmentation and Removal of Physiological Uptake
- Segmentation of Hotspots
- TTB Visualization and Statistical Analysis
- Manual Editing of Segmented Lesions and Saving Finalized RTst
- Warning Messages
- Multi-Timepoint Comparison within a Session
- Installation / Configuration Settings for Contour Sorting
- Licensing Requirements
- TTB Regions

Clinical Testing

LesionID Pro successfully completed performance testing on a clinically representative dataset to verify that the generated segmentations are adequate for use as an initial segmentation, helping to reduce user need for manual editing. The test evaluated the initial TTB segmentation generated by LesionID Pro, as compared to a pre-defined segmentation Agreement Standard based on physician approved segmentation. The datasets included both PSMA PET/CT and SPECT/CT studies, spanning factors various relevant to the evaluation of LesionID Pro's segmentation performance (e.g. radiotracers, disease burden, imaging systems)

The clinical testing included qualitative clinical reader evaluation. The evaluation was performed by United States board certified NM physicians through scoring of clinically representative PSMA PET/CT and SPECT/CT patient clinical studies. The readers were requested to assess whether the initial segmentation generated by LesionID Pro was of acceptable quality for clinical use in the context of PSMA PET and SPECT TTB segmentation and evaluation.

The testing and results did not raise new or different questions of safety and effectiveness than associated with predicate devices.

Conclusion

The subject device MIM – *LesionID Pro* has been developed according to MIM Software Inc.'s established design control process and software development life cycle. This includes risk management alongside verification and validation testing that includes testing of risk mitigations, as well as clinical performance testing.

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Therefore, based on all evidence gathered, it is MIM Software Inc.'s belief that MIM – *LesionID Pro* provides a device substantially equivalent to the predicate devices, and when used according to operating instructions, can be used safely and effectively. All the testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device. MIM Software Inc. considers the proposed device is substantially equivalent to the predicate devices.