October 26, 2026

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

Re: K261763
Trade/Device Name: MIM – KineticID
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 21, 2026
Received: September 21, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261763	?

Please provide the device trade name(s). ?

MIM – KineticID

Please provide your Indications for Use below. ?

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.

• Visualization and quantification of dynamic PET tracer pharmacokinetics.

• 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

K261763

510(k) SUMMARY

This 510(k) Summary of Safety and Effectiveness is submitted in accordance with the requirement of with 21 CFR Part 807.92.

Date	May 27, 2026
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 | MIM
Secondary Contact	Amy Yang, Director of Regulatory Affairs | MIM

Device Name

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

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Predicate Devices

Primary:	MIM – *LesionID Pro* MIM Software Inc. K251883 | December 11, 2025
Secondary:	DynamicIQ GE Medical Systems SCS K222895 | November 22, 2022

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 provides tools to visualize and quantify dynamic PET tracer pharmacokinetics.

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, 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.
- Visualization and quantification of dynamic PET tracer pharmacokinetics.
- 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.

Device Description

MIM – *KineticID* extends the features of the MIM software suite which was most recently 510(k)-cleared in the primary predicate device, MIM – *LesionID Pro* (K251883). The intended use and indications for use of the subject device are slightly modified from the predicate MIM device.

MIM software is designed for use in medical imaging and operates on Windows, Mac, and Linux computer systems. MIM – *KineticID* is an application built within the MIM software system which can be launched directly through a session within MIM or via a MIM Workflow.

MIM – *KineticID* is a software application that extends the functionality of the predicate device by enabling visualization and quantification of PET tracer pharmacokinetics based on dynamic PET imaging.

Comparison to Predicate Devices

The subject device, MIM – *KineticID*, extends the functionality of MIM software application (K251883), which is the primary predicate device representing the most recent 510(k)-clearance that includes the full suite of cumulative functionalities available within MIM software.

MIM – *KineticID* provides optional add-on features to the currently distributed version of MIM Encore, a data management, viewing, and advanced quantitation solution for medical imaging in nuclear medicine and radiology. Software features within MIM Encore were originally 510(k)-cleared in MIM 4.1 (SEASTAR) (K071964) and have since been iterated on in subsequent 510(k) submissions, including the primary predicate device, MIM – *LesionID Pro* (K251883).

Besides the addition of the PET tracer pharmacokinetics visualization and quantification features that are the primary subject of this 510(k) submission, the only other minor change to the MIM software application compared to MIM – *LesionID Pro* (K251883) is the inclusion of the new "Display Editor," a feature that allows users more flexibility in configuring session page layouts in MIM Workflows.

The GE HealthCare DynamicIQ (K222895) software package is a secondary predicate device. No changes have been made to DynamicIQ between the initial 510(k)-clearance in 2022 and this 510(k) submission. This device has the same intended use and technological characteristics as the features added to the subject device.

While this secondary predicate device specifically calls out its ability to support only one radiotracer (FDG), MIM – *KineticID* indiscriminately supports all tracers that can be modeled as irreversible. The subject device is not limited to, nor specifically focused on, FDG-based applications. Additionally, MIM – *KineticID* indiscriminately supports all camera manufacturers since compatibility is achieved through standard DICOM parsing and is not contingent on vendor-specific private tags, while DynamicIQ specifically supports GE HealthCare scanners only. Additionally, the MIM – *KineticID* application extends the functionality of the GE Healthcare DynamicIQ software package by adding the ability to generate an R^2 parametric image based off of the linear fit of the Patlak graph.

While the implementation of the processing and aspects of some algorithms may vary between the subject and predicate software devices, the core functionalities remain the same.

Substantial Equivalence Discussion

The table below summarize the substantive feature / technological differences between the subject device and predicate devices.

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

ITEM	SUBJECT DEVICE: **MIM Software Inc.** ***MIM – KineticID***	PRIMARY PREDICATE DEVICE: **MIM Software Inc.** **MIM – *LesionID Pro*** **(K251883)**	SECONDARY PREDICATE DEVICE: **GE HealthCare** **DynamicIQ** **(K222895)**	Discussion of Similarities / Differences between Subject Device and Predicate Devices
Operating Platform	Microsoft Windows, Apple® OSX, Linux-based OS	Microsoft Windows, Apple® OSX, Linux-based OS	Microsoft Windows, Apple® OSX Linux-based Server OS, Advantage Workstation (AW) Server 3.2	Identical – to primary predicate MIM device
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	Identical – to primary predicate MIM device
Input data for feature-specific processing	Dynamic PET, static PET, CT, MR, and other DICOM modalities	CT, NM, PET, and other DICOM modalities	Dynamic PET, static PET, and CT	Substantially Equivalent Compared to the predicate DynamicIQ device, MR has been added as an optional input for viewing or aiding segmentation within the subject device. The predicate MIM device can generally support processing for a variety of DICOM modalities as discussed in the above row, "Supported Image Modalities," while MIM – *LesionID Pro* specifically processes a more limited scope of images via its associated MIM Workflow.
Injection time QA	Yes Software performs a search of the dynamic input data DICOM for injection time tags and returns the value as the	Yes DICOM tag searching is available to be configured as needed. Specific applications vary.	Yes Software performs a search of the dynamic input data DICOM for injection time tags and returns the value as the	Substantially Equivalent No change in methods from the predicate devices. Primary MIM predicate device methods are used to accomplish the specific use case for injection time QA as the secondary DynamicIQ predicate

ITEM	SUBJECT DEVICE: **MIM Software Inc.** ***MIM – KineticID***	PRIMARY PREDICATE DEVICE: **MIM Software Inc.** **MIM – *LesionID Pro*** **(K251883)**	SECONDARY PREDICATE DEVICE: **GE HealthCare** **DynamicIQ** **(K222895)**	Discussion of Similarities / Differences between Subject Device and Predicate Devices
	radiopharmaceutical start time variable. If the DICOM returns a blank or null value, the software prompts the user to enter date and time which is assigned as the radiopharmaceutical start time variable.		radiopharmaceutical start time variable. If the DICOM returns a blank or null value, the software prompts the user to enter date and time which is assigned as the radiopharmaceutical start time variable.	device.
Generation of user-specified summed static series from dynamic series	Yes	Yes	Yes	Substantially Equivalent The subject and predicate devices allow users to define the range of dynamic series frames (based on start and end times) for creating the summed static series. The subject device provides this configurable option within Workflow Preferences, while the predicate devices offer this function directly within the UI.
Decay correction QA	Yes Software performs a search of the dynamic input data DICOM for decay correction tags and returns the value as the decay correction time variable. If the DICOM returns a blank value or value that does not correspond to the time of injection, the software performs decay correction based on isotope half-life to the time of injection to generate a decay-corrected series.	Yes DICOM tag searching is available to be configured as needed. Image decay correction is also available. Specific applications vary.	Yes Software performs decay correction on dynamic input data as necessary.	Substantially Equivalent The subject device uses the existing framework of the primary predicate MIM device to provide DICOM tag searching and image decay correction for the purposes of decay correction QA, matching the use case and processing within the predicate DynamicIQ device.

ITEM	SUBJECT DEVICE: **MIM Software Inc.** ***MIM – KineticID***	PRIMARY PREDICATE DEVICE: **MIM Software Inc.** **MIM – *LesionID Pro*** **(K251883)**	SECONDARY PREDICATE DEVICE: **GE HealthCare** **DynamicIQ** **(K222895)**	Discussion of Similarities / Differences between Subject Device and Predicate Devices
Image fusion / registration	Yes	Yes	Yes	Identical The subject and predicate devices allow image fusions. There are no changes to registration tools between the subject and predicate MIM devices. The specific use case for the subject and predicate DynamicIQ devices is to allow PET/CT (or PET/MR, not available in the predicate DynamicIQ device) registration for user review and segmentation assistance.
Manual segmentation tools and contour processing for multiple ROIs	Yes	Yes Various contouring tools are available. Specific applications vary.	Yes	Identical The subject and predicate devices allow manual user segmentation and contour processing for multiple ROIs. There are no changes to contouring tools between the subject and predicate MIM devices. User creation of Input Function (IF) ROI(s) is the specific use case for segmentation in the subject and predicate DynamicIQ devices. IF ROI(s) are propagated from the summed series to the dynamic series. Specific contouring tools are presented within the MIM Workflow for KineticID to facilitate efficient manual segmentation.
Generation and review of time-activity curves (TACs)	Yes	Yes Users can generate TACs from applicable PET and NM images. Specific applications vary.	Yes	Substantially Equivalent The subject device uses the existing framework of the primary predicate MIM device to provide TAC generation for the purposes of assessing the Input Function, matching the use case and processing within the predicate DynamicIQ device.
Patlak parameters	Yes	No	Yes	Identical – to secondary predicate DynamicIQ device

ITEM	SUBJECT DEVICE: **MIM Software Inc.** ***MIM – KineticID***	PRIMARY PREDICATE DEVICE: **MIM Software Inc.** **MIM – *LesionID Pro*** **(K251883)**	SECONDARY PREDICATE DEVICE: **GE HealthCare** **DynamicIQ** **(K222895)**	Discussion of Similarities / Differences between Subject Device and Predicate Devices
				The subject device uses the existing framework of the primary predicate MIM device (General Preferences, Workflow Preferences, and the Notifications window) to allow for user configuration of Patlak parameters identical to the secondary predicate device. Specifically including the following parameters: • Summed Image parameters • Fit Input Function parameters • RBC/Plasma correction parameters • Parametric volume parameters • Relative Patlak parameters
Patlak analysis and review	Yes Software applies Patlak parameters to determine the Patlak model (Absolute vs. Relative) and generates / displays the parametric images (K_i, V_0, MR_{FDG}, R^2).	No	Yes Software applies Patlak parameters to determine the Patlak model (Absolute vs. Relative) and generates / displays the parametric images (K_i, V_0, MR_{FDG}).	Substantially Equivalent – to secondary predicate DynamicIQ device Both the subject device and the secondary predicate DynamicIQ device provide the capability to review parametric images generated from Patlak analysis based on identical Patlak modeling. The subject device additionally includes functionality to generate an R^2 parametric image that provides a volumetric visual of the linear fit of the Patlak model.
Ability to save and export results	Yes	Yes MIM Workflows can be configured as buttons within MIM sessions to perform various tasks. Specific applications vary. Users can also select	Yes	Identical MIM Workflow buttons are used in both the subject device and primary predicate MIM device to facilitate certain user actions, such as saving results, as needed. DynamicIQ also provides the ability for users to save results.

ITEM	SUBJECT DEVICE: **MIM Software Inc.** ***MIM – KineticID***	PRIMARY PREDICATE DEVICE: **MIM Software Inc.** **MIM – *LesionID Pro*** **(K251883)**	SECONDARY PREDICATE DEVICE: **GE HealthCare** **DynamicIQ** **(K222895)**	Discussion of Similarities / Differences between Subject Device and Predicate Devices
		buttons in the inherent MIM UI to save and export any DICOM or MIM objects (e.g., MIM sessions).		
Ability to re-launch processing and make edits prior to results regeneration	Yes	Yes MIM Workflows can be configured as buttons within MIM sessions to perform various tasks. Specific applications vary. Users can also select buttons in the inherent MIM UI to launch MIM Workflows directly from an open MIM session (thus allowing re-processing).	Yes	Identical MIM Workflow buttons are used in both the subject device and primary predicate MIM device to facilitate certain user actions, such as re-launching processing, as needed. DynamicIQ also provides the ability for users to re-launch and regenerate results.
User-editable page layouts	Yes – via “Display Editor” tools	Yes – manually within MIM sessions	No	Substantially Equivalent – to primary predicate MIM device The subject device adds the “Display Editor” to provide users with the ability to permanently configure page layouts for MIM Workflows via Workflow Preferences, while the predicate MIM device only allows users to make temporary modifications to page layouts within open MIM sessions.

The comparison chart above provides evidence to facilitate the substantial equivalence determination between the subject device, MIM – KineticID, and the predicate devices. The primary predicate device, MIM – *LesionID Pro* (K251883), serves as the most recently 510(k)-cleared iteration of the MIM software device. The features of the subject device are closely aligned with functionality present in both primary and secondary predicate devices.

The substantial equivalence has been demonstrated by:

- Review of the proposed labeling included in this 510(k) and comparison / review of the proposed Indications for Use demonstrate that fall within the intended use of the predicate device. There are no new questions / concerns raised related to safety and effectiveness.
- The different technological characteristics do not raise different questions / concerns related to safety and effectiveness than the predicate device, and the device is as safe and effective as the legally marketed predicate device as demonstrated by:
    - Development under MIM Software's quality management system and design control activities, including risk management and the software development lifecycle (Software Documentation).
    - Software verification and validation without unexpected results (Software Documentation).

Testing and Performance Data

Verification testing has been completed for each design requirement to confirm that the specifications (outputs) meet the input requirements. Testing includes the verification of functional requirements, user interaction, user interface, and error handling. Testing was performed using a test environment simulating the real-use case environment in which users are expected to run the software in accordance with the system's operating and hardware requirements.

Verification tests are categorized as follows:

- KineticID – License Requirements
- KineticID – MIM Application (In-Session Tool):
    - Absolute Patlak Analysis Mode
    - Relative Patlak Analysis Mode
    - Global Configuration
    - Input Detection
- KineticID – MIM Workflow:
    - Absolute Patlak Analysis 1st Launch
    - Absolute Patlak Analysis Relaunch
    - Relative Patlak Analysis 1st Launch
    - Relative Patlak Analysis Relaunch
    - Different Input – Injection Time & Decay Correction Verification

- Different Input – Static PT/CT is present
- Workflow Preferences

Validation testing has been completed to ensure that the application meets the user needs and intended use of the software. In addition to system testing, validation of the algorithms used in the application that could not be verified within the functional testing was also completed.

Validation tests are categorized as follows:

- MIM-generated parametric maps vs. simulated data
- MIM-generated Input Function vs. simulated Input Function
- MR_{FDG} conversion from K_i on parametric maps
- MIM-generated relative Patlak parametric maps vs. simulated data
- Scaling uniformity between relative and absolute Patlak for FDG PET patient data
- Scaling uniformity between relative and absolute Patlak for PSMA PET patient data
- Scaling uniformity between relative and absolute Patlak for total body PET patient data

All tests were completed successfully and passed predefined acceptance criteria. Testing results confirm MIM – *KineticID* has been designed as intended and is suitable for clinical use.

Conclusion

The subject device, MIM – *KineticID*, 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.

Therefore, based on all evidence gathered, it is MIM Software Inc.’s belief that MIM – *KineticID* 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.