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

October 23, 2024

Re: K243012
Trade/Device Name: MIM - Symphony HDR Fusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 27, 2024
Received: September 27, 2024

Dear Sydney Lindner:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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

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

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243012

Device Name

MIM – Symphony HDR Fusion

Indications for Use *(Describe)*

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include but are not limited to, CT, MR, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

• Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.

• Create, display and print reports from medical images.

• Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.

• Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.

• Localization and definition of objects such as tumors and normal tissues in medical images.

• Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

• Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.

• Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).

• Calculating absorbed radiation dose as a result of administering a radionuclide.

• Assist with the planning and evaluation of ablation procedures by providing visualization and analysis, including energy zone visualization through the placement of virtual ablation devices validated for inclusion in MIM-Ablation. The software is not intended to predict specific ablation zone volumes or predict ablation success.

When using the device clinically, within the United States, the user should only use FDA approved radiopharmaceuticals. If 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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25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

510(k) Summary
(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:	Sydney Lindner
Date Summary Prepared:	September 25, 2024

Device Name

Trade Name:	MIM – *Symphony HDR Fusion*
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

K232862	MIM – *Monte Carlo Dosimetry*	MIM Software Inc.

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

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. 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.

25800 Science Park Drive - Suite 180
Cleveland, OH 44122
866-421-2536
www.mimsoftware.com

Indications for Use

MIM software is used by trained medical professionals as a tool to aid in evaluation and information management of digital medical images. The medical image modalities include but are not limited to, CT, MR, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0. MIM assists in the following indications:

• Receive, transmit, store, retrieve, display, print, and process medical images and DICOM objects.

• Create, display and print reports from medical images.

• Registration, fusion display, and review of medical images for diagnosis, treatment evaluation, and treatment planning.

• Evaluation of cardiac left ventricular function and perfusion, including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction.

• Localization and definition of objects such as tumors and normal tissues in medical images.

• Creation, transformation, and modification of contours for applications including, but not limited to, quantitative analysis, aiding adaptive therapy, transferring contours to radiation therapy treatment planning systems, and archiving contours for patient follow-up and management.

• Quantitative and statistical analysis of PET/SPECT brain scans by comparing to other registered PET/SPECT brain scans.

• Planning and evaluation of permanent implant brachytherapy procedures (not including radioactive microspheres).

• Calculating absorbed radiation dose as a result of administering a radionuclide.

• Assist with the planning and evaluation of ablation procedures by providing visualization and analysis, including energy zone visualization through the placement of virtual ablation devices validated for inclusion in MIM-Ablation. The software is not intended to predict specific ablation zone volumes or predict ablation success.

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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 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.

Device Description

MIM – *Symphony HDR Fusion* extends the existing features and capabilities of MIM – *Monte Carlo Dosimetry* (K232862) by offering enhanced capabilities to better support the High Dose Rate (HDR) brachytherapy workflow. It is designed for use in medical imaging and operates on Windows, Mac, and Linux computer systems. The intended use and indications for use in MIM - *Symphony HDR Fusion* are unchanged from the predicate device MIM – *Monte Carlo Dosimetry*.

MIM – *Symphony HDR Fusion* is a standalone software application within the MIM software suite that uses the existing functionality of the predicate device, applied now in the context of a High Dose Rate (HDR) brachytherapy clinical workflow.

MIM – *Symphony HDR Fusion* leverages the foundational functionalities that were introduced in the predicate device to support Low Dose Rate (LDR) brachytherapy clinical workflows. These features are extended with necessary enhancements and optimizations to optimally support the HDR workflow. Specifically, the subject device MIM – *Symphony HDR Fusion* provides the following core processes:

- **Reslicing and Predictive Fusion** presents data to inform the user's placement of medical devices (in this case, brachytherapy applicators). MIM receives and displays 2D images from a Trans-rectal Ultrasound (TRUS) probe and overlays contours from the registered pre-op image volume. The user is able to modify the position of the TRUS probe in the patient in order to match the visible pre-op contours. The user may also manually adjust the registration using software tools.

- **Ultrasound Capture:** MIM receives an image feed from an US machine and position information from a stepper that holds the TRUS probe. The 2D TRUS

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images are processed into 3D image volumes—enabling their registration, fusion display, and storage as DICOM objects.

- **Catheter Digitization** provides tools for the user to localize and define HDR brachytherapy applicators (catheters) in medical images.
- **Registration Chaining** allows the user to transfer information (contours) from the pre-op image (typically MR) through to the final planning image (US or CT). This is achieved using existing rigid registration tools from the predicate device to sequentially register each new image to its immediate predecessor in the clinical workflow.
- **Export Data**: The end of the MIM – *Symphony HDR Fusion* workflow is to export the final planning image and user-defined structures—including organs and brachytherapy applicator models—into DICOM files for use in third-party radiation therapy treatment planning systems. Structured reports may also be created.

Comparison to Predicate

ITEM	Subject Device: MIM - *Symphony HDR Fusion* (TBD)	Predicate Device: MIM – *Monte Carlo Dosimetry* (K232862)
Clearance Date	TBD	May 13, 2024
Intended Use	(Identical to predicate. See above for complete list.)	See above
Indications for Use	(Identical to predicate. See above for complete list.)	See above
Operating Platform	Microsoft Windows, Apple® OS X, Linux-based OS	Microsoft Windows, Apple® OS X, Linux-based 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
Receive, transmit, display, general manipulation (window/level, pan, zoom, cross-hairs, slice navigation), and co-registration of medical images	Yes	Yes

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ITEM	Subject Device: MIM - *Symphony HDR Fusion* (TBD)	Predicate Device: MIM – *Monte Carlo Dosimetry* (K232862)
Image re-slicing and reorientation to a user-defined angle for planning	Yes	Yes
Read, write, render, and transmit DICOM files, including structure models and point sequences representing medical applicators (e.g. catheters or needles)	Yes – including **HDR** brachytherapy RTPlans	Yes – unchanged from MIM 5.2 (Brachy) (K103576)
Receive 2D ultrasound images for storage and processing into 3D image volumes that are recorded as DICOM objects	Yes	Yes
Generate digitized models of medical devices (e.g. applicators) via user interaction with medical images	Yes	Yes
Transfer contours (DICOM RTstruct data) between medical images that have been co-registered for the purpose of facilitating radiation therapy treatment.	Yes	Yes
Dose planning and evaluation of dose distributions for brachytherapy procedures.	Yes – unchanged from MIM 5.2 (Brachy) (K103576). Dose planning for LDR brachytherapy only. Loads and reviews dose (but does not calculate or optimize dose) for HDR brachytherapy.	Yes – for LDR brachytherapy only.

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www.mimsoftware.com

Testing and Performance Data

Verification and validation tests were performed for each of the five core features of MIM – *Symphony HDR Fusion*:

- Reslicing and Predictive Fusion
- Ultrasound Capture
- Catheter Digitization
- Registration Chaining
- Data Export

The testing methods include both internal verification by MIM's own qualified testers, and also external validation by trained medical professionals with extensive experience in HDR brachytherapy.

Each individual feature met the acceptance criteria defined for the verification and validation tests, and the entire software product was determined to be safe and effective for clinical use.

Conclusion

MIM – *Symphony HDR Fusion* 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, from all evidence gathered, it is MIM Software Inc.'s belief that MIM – *Symphony HDR Fusion* provides a device substantially equivalent to the predicate device, and when used according to operating instructions, can be used safely and effectively.