



May 27, 2026

Philips Medical Systems Nederland B.V.
Carmit Shmuel
Regulatory Affairs Manager and Site Lead
Philips Medical Systems Technologies, Ltd.
Advanced Technology Center, Matam, Bldg. 34
Haifa, 3100202
Israel

Re: K260207

Trade/Device Name: Multimodality Simulation Workspace (MM Sim) (v1.0.0)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: MUJ
Dated: January 22, 2026
Received: January 23, 2026

Dear Carmit Shmuel:

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 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,

A handwritten signature in black ink, reading "Lora D. Weidner". The signature is fluid and cursive. A large, light blue "FDA" watermark is visible in the background behind the signature.

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

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.

K260207

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Please provide the device trade name(s).

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Multimodality Simulation Workspace (MM Sim) (v1.0.0)

Please provide your Indications for Use below.

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Multimodality Simulation Workspace (MM Sim) Suite is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation of treatments such as those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy).

It provides tools to view existing contours, create, edit, modify, copy contours of regions of the body, such as but not limited to, skin outline, targets and organs-at-risk. It also provides functionalities to create simple geometric treatment plans. Contours, images and treatment plans can subsequently be exported to a Treatment Planning System.

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](#))

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510(K) SUMMARY

(in accordance to 21 CFR § 807.92)

Date Prepared: May 4, 2026

SUBMITTER INFORMATION

Applicant	Philips Medical Systems Nederland B.V.
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Secondary Contact	Veronica Padharia Principal Regulatory Affairs Specialist Email: veronica.padharia@philips.com Phone: +1 (630) 917-1160

DEVICE IDENTIFICATION

Subject Device	
Trade Name	Multimodality Simulation Workspace (MM Sim)
Version	v1.0.0
Common Name	MM Sim
Classification Name	Radiation therapy simulation software
Classification Regulation	21 CFR 892.5050
Classification Panel	Medical charged-particle radiation therapy system
Device Class	Class II
Product Code	MUJ

Predicate Device	
Trade Name	syngo.RT Image Suite
Manufacturer	Siemens Medical Solutions USA, Inc
510(k) Clearance	K232799
Classification Name	Radiation therapy simulation software
Classification Regulation	21 CFR 892.5050
Classification Panel	Medical charged-particle radiation therapy system
Device Class	Class II
Product Code	MUJ

INTENDED USE / INDICATIONS FOR USE STATEMENT

INTENDED USE

Multimodality Simulation Workspace (MM Sim) is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation of treatments such as those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy).

INDICATIONS FOR USE

Multimodality Simulation Workspace (MM Sim) is a 3D and 4D image visualization, multi-modality manipulation and contouring tool that helps the preparation of treatments such as those performed with radiation (for example, Brachytherapy, Particle Therapy, External Beam Radiation Therapy). It provides tools to view existing contours, create, edit, modify, copy contours of regions of the body, such as but not limited to, skin outline, targets and organs-at-risk. It also provides functionalities to create simple geometric treatment plans. Contours, images and treatment plans can subsequently be exported to a Treatment Planning System.

DEVICE DESCRIPTION

Multimodality Simulation Workspace (MM Sim) is a software-only medical device (Software as a Medical Device, SaMD) designed to support radiation therapy simulation and preparation workflows. MM Sim provides three-dimensional (3D) and four-dimensional (4D) image visualization, multimodality image manipulation, and contouring tools using previously acquired medical image data. The software interoperates with external imaging systems, laser positioning systems, Picture Archiving and Communication Systems (PACS), and Oncology Information Systems (OIS) using DICOM-compliant data exchange within a healthcare institution’s controlled network environment. MM Sim may operate as an off-console standalone simulation application and can be accessed via a CT console interface or through a secure remote desktop client. MM Sim does not acquire images, emit radiation, calculate radiation dose, perform treatment plan optimization, control treatment delivery, or directly interface with patients. All outputs generated by MM Sim require user review prior to downstream clinical use.

TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE

MM Sim and the predicate device, syngo.via RT Image Suite (K232799), have the same fundamental technological characteristics. Both are software-based medical devices that operate on medical image data to provide 3D and 4D multimodality image visualization, image registration, anatomical contouring, and export of simulation-related data for use in radiation therapy workflows. Both devices utilize established principles of medical image processing, visualization, and DICOM-compliant data communication and are intended for use by trained medical professionals in radiation oncology environments. Neither device performs radiation dose calculation, treatment plan optimization, or treatment delivery, and neither device directly interfaces with patients. Table 1 below provides a high-level comparison of key functional and technological characteristics between the subject and predicate device.

Table 1 – Technological Comparison between Subject and Predicate Device			
Comparison Element	Predicate Device syngo.via RT Image Suite (K232799)	Subject Device Multimodality Simulation Workspace (MM Sim)	Conclusion
Intended Use / Indications	Supports radiation therapy simulation and treatment preparation through multimodality image visualization, contouring, and data export	Supports radiation therapy simulation and treatment preparation through multimodality image visualization, contouring, and data export	Same

Device Type	Software-only medical device (SaMD)	Software-only medical device (SaMD)	Same
Fundamental Scientific Technology	Medical image processing, visualization, registration, contouring, and DICOM-based data exchange	Medical image processing, visualization, registration, contouring, and DICOM-based data exchange	Same
Image Visualization (3D/4D)	Supports 3D and 4D multimodality image visualization	Supports 3D and 4D multimodality image visualization	Same
Image Registration	Rigid and deformable image registration across modalities	Rigid and deformable image registration across modalities	Same
Manual Contouring	Manual and semi-automatic contouring tools	Manual and semi-automatic contouring tools	Same
Assistive Segmentation	Deep learning-based auto-segmentation for supported anatomies	Atlas-based and model-based assistive segmentation for supported anatomies	Different
Simulation Geometry & Planning Support	Supports creation of simple geometric treatment plans for simulation purposes	Supports creation of simple geometric treatment plans for simulation purposes	Same
4D CT-Derived Datasets	Supports representative phase selection from 4D CT datasets	Supports representative phase selection and generation of mid-ventilation and mid-position datasets	Similar
DICOM RT Import/Export	Supports DICOM RT structure and plan import/export	Supports DICOM RT structure and plan import/export	Same
Workflow Support Features	Provides workflow assistance using predefined templates	Provides workflow assistance using configurable navigation pathways	Similar
Dose Calculation / Treatment Delivery	Not performed	Not performed	Same

MM Sim includes modifications and enhancements to certain software features compared to the predicate device, such as additional image processing options, workflow support tools, and segmentation methods. These differences represent alternative or refined implementations of established technologies and do not alter the fundamental scientific principles, intended use, or clinical role of the device. All outputs generated by MM Sim require user review and approval prior to clinical use.

NON-CLINICAL PERFORMANCE TESTING

Nonclinical performance testing was conducted to support the determination of substantial equivalence for Multimodality Simulation Workspace (MM Sim). Testing was planned and executed using a risk-based approach appropriate for a software-only medical device supporting radiation therapy simulation workflows.

The scope of nonclinical performance testing included system-level evaluation of representative use scenarios, covering the following performance domains:

- Image data handling and interoperability, including import, processing, and export of DICOM-compliant image and simulation datasets;
- User-driven visualization and interaction, including multi-modality image viewing, registration behavior, and contour creation and modification;
- Workflow execution, including end-to-end simulation preparation steps performed under simulated clinical use conditions;
- Data integrity and output correctness, including generation and export of simulation geometry, reference data, and downstream-compatible datasets for treatment planning systems.

In addition, image quality characteristics relevant to simulation workflows were evaluated using phantom-based and representative datasets under controlled and matched conditions. Evaluated characteristics included spatial resolution behavior, noise characteristics, uniformity across the field of view, artifact behavior, and extended field-of-view (EFOV) performance where applicable. Image

quality evaluation was designed to confirm suitability for simulation and preparation workflows and was not intended to support diagnostic interpretation.

Acceptance criteria for performance testing were derived from system design specifications, intended use considerations, comparative performance of the predicate device, and applicable nonclinical benchmarks.

The results of nonclinical performance testing demonstrated that MM Sim performs as intended and is substantially equivalent to the predicate device with respect to safety and performance. Nonclinical testing activities were conducted in accordance with applicable FDA guidance and FDA-recognized consensus standards, including IEC 62304 for software lifecycle processes and ISO 14971 for risk management, as appropriate.

MM Sim does not include deep learning–based autonomous auto-contouring functionality; therefore, nonclinical performance testing focused on workflow-level validation and user-assisted segmentation rather than quantitative AI algorithm performance evaluation.

Table 2 below summarizes the non-clinical performance testing conducted for the modified software features and principal system functions of MM Sim. For each feature category, the table outlines the objective of testing, feature-specific test method, high-level acceptance criteria, and overall results.

Table 2 – Non-Clinical Performance Testing Summary				
Modified Feature	Objective of Testing	Test Method	Acceptance Criteria	Results
Mid-Position (Mid-P) Image Set	Verify correct generation of derived Mid-Position datasets from 4D CT phase data and assess image quality and usability under simulated clinical use conditions.	Requirements-based verification and workflow-based validation using representative 4D CT datasets to evaluate Mid-P dataset generation, phase/reference image handling, generation constraints, progress indication and processing time, image registration support, and DICOM export. Testing was supplemented by independent expert review of Mid-P image quality, interpretability, artifact behavior, and contouring/simulation suitability.	All evaluated datasets must meet predefined image quality thresholds for suitability in contouring and simulation workflows.	Independent expert review confirmed all evaluated cases met predefined success criteria; all cases rated ≥3, with average ratings of 4.7, demonstrating suitability for contouring and simulation workflows.
Mid-Ventilation (Mid-V) Identification	Confirm algorithm-assisted identification of representative respiratory phase operates correctly within intended workflow.	Requirements-based verification and workflow-based validation using representative 4D CT datasets to evaluate Mid-V phase identification, selected phase handling, identification constraints, progress indication and processing time, reporting of Mid-V identification records, dataset integrity, workflow execution, and DICOM export behavior.	Workflow execution, dataset integrity, and DICOM export behavior must meet predefined functional and system requirements.	System-level validation demonstrated all validation cases met acceptance criteria under simulated clinical use conditions.
Navigation Pathway Functionality	Verify user-defined workflow recording and execution functions operate as intended and remain user-initiated.	Requirements-based verification and simulated-use validation to evaluate configured workflow execution, user controls, pause/resume behavior, status handling, persistence, access protections, and user-initiated operation.	Recorded workflow sequences must execute accurately, preserve data integrity, and require explicit	Validation testing confirmed accurate execution of recorded workflows; all acceptance criteria were met.

			user initiation.	
Atlas-Based and Model-Based Assistive Segmentation	Confirm assistive segmentation workflows generate stable, user-editable contour suggestions and maintain output integrity for downstream use.	Requirements-based verification and workflow-based validation using representative image datasets to evaluate segmentation execution, supported anatomical regions and model configurations, generation of user-editable contour outputs, user review and editing workflow, contour data integrity, and DICOM RT export.	Contour generation, data integrity, and DICOM RT export must meet predefined functional specifications; outputs must remain user-editable.	System-level validation confirmed correct segmentation workflow behavior across representative datasets; all acceptance criteria were met.
Principal System Functions (Visualization, Registration, Manual Contouring, DICOM RT Import/Export, Intensity Projection, Coordinate Export)	Confirm core simulation workflows operate correctly under simulated clinical use conditions.	System-level requirements-based verification and simulated-use validation to evaluate visualization, registration, manual contouring, DICOM RT import/export, intensity projection, coordinate export, interoperability, data integrity, and end-to-end workflow execution under simulated clinical use conditions.	Functional correctness, data integrity, and interoperability must meet system design specifications.	System-level validation confirmed all principal workflows met predefined acceptance criteria.

The following nonclinical evidence categories are not applicable to MM Sim due to its nature as a software-only medical device:

- Physical and mechanical characterization
- Chemical or material characterization
- Radiation safety
- Pyrogenicity
- Safety of materials of biological origin

CLINICAL TESTING

Not Applicable.

No clinical testing involving human subjects was conducted or relied upon to support the determination of substantial equivalence for MM Sim. Substantial equivalence was established based on nonclinical performance testing, which was sufficient to demonstrate safety and performance for the intended use.

RISK ANALYSIS

A risk analysis was performed for MM Sim in accordance with ISO 14971 and the Philips Quality Management System. Identified hazards and hazardous situations associated with the software were evaluated, and appropriate risk control measures were implemented to mitigate identified risks.

Verification and validation testing demonstrated that all defined risk control measures were correctly implemented and effective, and that all software requirements and specifications met their predefined acceptance criteria. Residual risks were evaluated and determined to be acceptable based on a benefit-risk assessment consistent with the device's intended use.

The results of software verification and validation activities support that MM Sim performs as intended and does not introduce new questions of safety or effectiveness when compared to the predicate device. The testing conducted is sufficient to support the determination of substantial equivalence.

CYBERSECURITY

Cybersecurity risk management, security architecture, verification and validation testing, and postmarket cybersecurity processes were addressed in accordance with applicable FDA guidance and recognized industry standards. Cybersecurity controls include authentication, authorization, data protection, audit logging, secure communications, and postmarket vulnerability management. Residual cybersecurity risks were assessed and determined to be acceptable for the intended use.

FDA-RECOGNIZED CONSENSUS STANDARDS

Philips conforms to the applicable FDA-recognized consensus standards identified in this submission:

Standard	Title	FDA Recognition #
IEC 62304	Medical device software – Software life cycle processes	13-79
ISO 14971	Medical devices – Application of risk management to medical devices	5-125
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	5-129
NEMA PS 3.1 – PS 3.20	Digital Imaging and Communications in Medicine (DICOM) Set	12-363
IEC TIR 80002-1	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software	13-34
ISO 15223-1	Medical devices – Symbols to be used with information supplied by the manufacturer	5-134
IEC 82304-1	Health software – Part 1: General requirements for product safety	13-97
ISO 20417	Medical devices – Information to be supplied by the manufacturer	5-135
IEC 81001-5-1	Health software & health IT systems safety, effectiveness and security – Security activities in the product lifecycle	13-122
IEC 62083	Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems	12-217
IEC 61217	Radiotherapy equipment – Coordinates, movements and scales	12-267

CONCLUSION

Based on the information provided in this submission, including nonclinical performance testing and comparative analysis, Multimodality Simulation Workspace (MM Sim) is substantially equivalent to the legally marketed predicate device, syngo.via RT Image Suite (K232799), with respect to intended use, technological characteristics, safety, and effectiveness.