



July 3, 2025

Siemens Medical Solutions USA, Inc.
Clayton Ginn
Regulatory Affairs Professional
2501 North Barrington Road
Hoffman Estates, Illinois 60192

Re: K251528

Trade/Device Name: syngo.via MI Workflows; Scenium; syngo MBF
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 19, 2025
Received: May 19, 2025

Dear Clayton Ginn:

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent watermark of the letters 'FDA'.

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.

K251528

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Please provide the device trade name(s).

?

syngo.via MI Workflows;
Scenium;
syngo MBF

Please provide your Indications for Use below.

?

syngo.via molecular imaging (MI) workflows comprise medical diagnostic applications for viewing, manipulation, quantification, analysis and comparison of medical images from single or multiple imaging modalities with one or more time-points. These workflows support functional data, such as positron emission tomography (PET) or nuclear medicine (NM), as well as anatomical datasets, such as computed tomography (CT) or magnetic resonance (MR). syngo.via MI workflows can perform harmonization of SUV (PET) across different PET systems or different PET reconstruction methods.

syngo.via MI workflows are intended to be utilized by appropriately trained health care professionals to aid in the management of diseases, including those associated with oncology, cardiology, neurology, and organ function. The images and results produced by the syngo.via MI workflows can also be used by the physician to aid in radiotherapy treatment planning.

Please select the types of uses (select one or both, as applicable).

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

?

510(k) Summary

1. Identification of the Submitter

K251528

Submitter / Primary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Secondary Contact Person	Brian Wui Regulatory Affairs hansong.wui@siemens-healthineers.com +1 (865) 367-4337
Applicant Name and Address	Siemens Medical Solutions, Inc. USA 2501 North Barrington Road Hoffman Estates IL, 60192, USA Establishment Registration Number: 1423253
Date of Preparation	May 15 th , 2025

2. Device Name and Classification

Product Trade Name:	syngo.via MI Workflows; Scenium; syngo MBF
Common Name:	Medical image management and processing system
Classification Name:	Automated Radiological Image Processing Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QIH

3. Predicate Devices

Primary Predicate Device:

Product Trade Name:	syngo.via MI Workflows; Scenium; syngo MBF
510(k) Number	K242275
Clearance Date	08/30/2024

Common Name:	Medical image management and processing system
Classification Name:	Automated Radiological Image Processing Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QIH

Reference Predicate Device:

Product Trade Name:	<i>syngo.via</i> MI Workflows; Scenium; syngo MBF
510(k) Number	K232000
Clearance Date	11/28/2023
Common Name:	Medical image management and processing system
Classification Name:	Automated Radiological Image Processing Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	Class II
Product Code:	QIH

4. Device Description

syngo.via MI Workflows (including Scenium and syngo MBF applications) is a multi-modality post-processing software only medical device intended to aid in the management of diseases, including those associated with oncology, cardiology, neurology, and organ function. The *syngo.via* MI Workflows applications are part of a larger *syngo.via* client/server system which is intended to be installed on common IT hardware. The hardware itself is not seen as part of the *syngo.via* MI Workflows medical device.

The *syngo.via* MI Workflows software addresses the needs of the following typical users of the product:

- Reading Physician / Radiologist – Reading physicians are doctors who are trained in interpreting patient scans from PET, SPECT and other modality scanners. They are highly detail oriented and analyze the acquired images for abnormalities, enabling ordering physicians to accurately diagnose and treat scanned patients. Reading physicians serve as a liaison between the ordering physician and the technologists, working closely with both.

- **Technologist** – Nuclear medicine technologists operate nuclear medicine scanners such as PET and SPECT to produce images of specific areas and states of a patient's anatomy by administering radiopharmaceuticals to patients orally or via injection. In addition to administering the scan, the technologist must properly select the scan protocol, keep the patient calm and relaxed, monitor the patient's physical health during the protocol and evaluate the quality of the images. Technologists work very closely with physicians, providing them with quality-checked scan images.

The software has been designed to integrate the clinical workflow for the above users into a server-based system that is consistent in design and look with the base *syngo.via* platform and other *syngo.via* software applications. This ensures a similar look and feel for radiologists that may review multiple types of studies from imaging modalities other than Molecular Imaging, such as MR.

The *syngo.via* MI workflows software supports integration through DICOM transfers of positron emission tomography (PET) or nuclear medicine (NM) data, as well as anatomical datasets, such as computed tomography (CT) or magnetic resonance (MR).

Although data is automatically imported into the server based on predefined configurations through the hospital IT system, data can also be manually imported from external media, including CD, external mass storage devices, etc.

The Siemens *syngo.via* platform and the applications that reside on it, including *syngo.via* MI Workflows, are distributed via electronic medium. The Instructions for Use is also delivered via electronic medium.

syngo.via MI Workflows includes 2 workflows (*syngo.MM* Oncology and *syngo.MI* General) as well as the Scenium neurology software application and the *syngo* MBF cardiology software application which are launched from the OpenApps framework within the MI General workflow.

5. Indications for Use

syngo.via molecular imaging (MI) workflows comprise medical diagnostic applications for viewing, manipulation, quantification, analysis and comparison of medical images from single or multiple imaging modalities with one or more time-points. These workflows support functional data, such as positron emission tomography (PET) or nuclear medicine (NM), as well as anatomical datasets, such as computed tomography (CT) or magnetic resonance (MR). *syngo.via* MI workflows can perform harmonization of SUV (PET) across different PET systems or different PET reconstruction methods.

syngo.via MI workflows are intended to be utilized by appropriately trained health care professionals to aid in the management of diseases, including those associated with oncology, cardiology, neurology, and organ function. The images and results produced by the *syngo.via* MI workflows can also be used by the physician to aid in radiotherapy treatment planning.

6. Indications for Use Comparison to the Predicate Device

The indications for use are the same between the subject device and the primary predicate device.

7. Comparison of Technological Characteristics with the Predicate Device

syngo.via MI Workflows with software version VC10, Scenium with software version VE70, and *syngo* MBF with software version VB30 software provide the same technological characteristics in terms of materials, energy source, and control mechanisms when compared to the legally marketed predicate device since all devices are software only devices.

The software features have been modified in comparison to the predicate device to support enhanced device functionality.

The intended use, indications for use, and fundamental scientific technology for the subject device remains unchanged from the predicate device. No features present from the predicate device have been de-scoped.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Data Supported (PET, SPECT, CT, MR)
- Server/Client architecture
- Workflow Activities (preprocessing, evaluation and reading, reporting and storage)
- Feature Licensing Structure
- SUV values calculated

The following technological differences exist between the subject device and predicate devices.

syngo.via MI Workflows VC10:

MI General

- Improved Lung Segmentation in Anatomy Segmentation and Auto Lung 3D
- VQ Ratio and Subtraction Images for Auto Lung 3D
- General Masking Tool for PET/SPECT/GNM
- Deauville Score from MM Oncology
- Improved Liver Reference Region Placement
- CT Oncology Extensions
 - Basic Oncology Tools: Assisted Perpendicular (RECIST/WHO) and Nodule Marker (Lesion quantification / lung lesion segmentation)
 - Lung CAD
- Layout editing and User Presets updates
- Organ Processing Updates
 - CBF Image Creation and Display
 - GSA Liver
 - Cardiac Shunt

MM Oncology

- Extended Large Matrix CT Data Support
- Advanced Density Tool Enhancements for CT Segmentations
- SPP 2.0 Extended Support (DE Preprocessing, VNC/Iodine Fusion, DE Layouts)

Scenium VE70:

- No changes

syngo MBF VB30:

- No changes

Any differences in technological characteristics do not raise different questions of safety and effectiveness. Testing and validation are completed. Test results show that the subject devices are comparable to the predicate devices in terms of technological characteristics and safety and effectiveness and therefore are substantially equivalent to the predicate devices.

8. Non-Clinical and/or Clinical Test Summary & Conclusions

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

'Enhanced' software documentation per FDA's guidance document "Content of Premarket Submissions for Device Software Functions" issued in June, 2023 is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. The testing supports that all software specifications have met the acceptance criteria. Verification and validation testing substantiates all requirement and functional specifications, including specifications related to device hazards, and supports the claim of substantial equivalence.

Lung and Lung Lobe Segmentation

In addition to verification and validation testing, performance evaluation was conducted in order to ensure the safety and effectiveness of the lung lobe segmentation algorithm compared to the predicate device. The lung lobe segmentation algorithm was re-trained with additional data and is utilized within the Auto Lung 3D and Anatomy Segmentation features of the MI General workflow.

Quantitative evaluation of the segmentation results was performed using the commonly used overlap measure Dice coefficient (DSC). The algorithm was tested retrospectively on an independent cohort of 20 patients that were not part of training or tuning cohort. The test cohort was augmented compared to the predicate to include new subjects. Half of the patients in the test cohort were new and the other 50% were randomly selected from the predicate testing cohort. Performance was compared between the predicate and updated algorithms. In summary:

- I. No overlap of patients between training, tuning, and test cohorts.
- II. Relevant test cohort parameters are as follows:
 - ~50% male patients
 - Slice thickness ≤ 5 mm

- 50% of patients were from the US
- All patients from Siemens Scanner
- Adults, age > 21

Acceptance Criteria for organ segmentation in syngo.via MI Workflows:

- For new organs, the average Dice coefficient per organ shall be greater than 0.8 or the average symmetric surface distance (ASSD) per organ less than 2 voxel of worst slice thickness, i.e. 10 mm.
- For unchanged organs, the average Dice coefficient per organ shall be within +/-0.03 of the average Dice coefficient per organ of the predicate algorithm.
- For improved organs, the average Dice coefficient per organ shall be greater or equal than the average Dice coefficient per organ of the predicate algorithm.

The average Dice coefficient for the 20 subjects was higher for each lobe in the subject device than in the predicate device, although not greater than a +0.03 difference for all lobes.

The anatomy segmentation feature supports segmentation for a wide variety of organs. Since each organ utilizes a different model, the Dice-score on other organs (other than lungs and lung lobes) that were not retrained remained unchanged and this was verified by recalculating the Dice score with the new algorithm.

PERCIST Liver Reference Region Placement

Additionally, performance evaluation was conducted for the updated PERCIST Liver Reference Region placement. The algorithm takes as input the PET/CT image together with a binary liver mask and returns the coordinates of the reference region center.

The performance specifications for the binary liver mask used as input to the algorithm are detailed below. This AI/ML segmentation algorithm is the same segmentation algorithm as utilized in the Anatomy Segmentation feature of the reference predicate device (K232000).

The test data consisted of 20 patients. The patients were obtained from clinical partners in Europe and USA. The data was randomly selected using the following stratification:

- No overlap of patients between training, tuning, and test cohorts
- Adults, Age > 21
- ~50% male patients
- Slice thickness <= 5 mm
- All subject from Siemens Scanner

The acceptance criteria for the liver and all other organs supported by the anatomy segmentation feature is an average Dice coefficient greater than 0.8 or an average symmetric surface distance (ASSD) less than 10 mm. The liver met both criteria.

The performance evaluation for the updated PERCIST Liver Reference Region placement is detailed below.

In the first analysis conducted, the reference standard used to evaluate the subject device method performance consisted of liver VOI positioning obtained semi-automatically by two expert readers. The subject device algorithm was then compared to the reference standard and shown to yield results in better agreement with semi-automatic evaluation by expert readers compared with the method of placement used in the predicate device.

The second analysis conducted focused on PET/CT scans presenting foci with suspicious tracer uptake either in the liver or with spill over to the liver, evaluating the subject and predicate devices based on how often the PERCIST VOIs intersected the suspicious uptake masks identified by an expert reader. Out of 129 subjects included in the analysis, the subject device had fewer intersections (4 cases) compared to the predicate device (13 cases). As with the predicate device, the user can manually reposition the PERCIST liver reference region at any time.

Clinical Testing

Clinical testing was not conducted for this submission.

Conclusion

There are no differences in the Indications for Use, Intended Use, or Fundamental Technological Characteristics of the updated *syngo.via* MI Workflows software (including Scenium and syngo MBF) as compared to the currently commercially available *syngo.via* MI Workflows software (K242275).

Both the current and predicate devices are used for viewing, manipulation, quantification, analysis, and comparison of medical images from single or multiple imaging modalities with one or more time-points.

Additionally, the new features implemented within this release do not raise any new issues of safety and effectiveness as compared to the predicate device. The predicate devices were cleared based on the results of non-clinical testing including verification and validation. . The subject device is also validated using the same methods as used for the predicate devices. The non-clinical verification and validation demonstrate that the subject devices should perform as intended in the specified use conditions.

Based on this information, as well as the documentation in support of the modifications, the subject devices with the modifications outlined in this application are substantially equivalent to the predicate devices.