November 28, 2023

Siemens Medical Solutions USA, Inc.
% Clayton Ginn
Official Applicant
2501 North Barrington Road
Hoffman Estates, Illinois 60192

Re: K232000
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: October 25, 2023
Received: October 25, 2023

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.

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
OHT 8: 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232000

Device Name

syngo.via MI Workflows;
Scenium;
syngo MBF

Indications for Use *(Describe)*

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.

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.

510(k) Summary

1. Identification of the Submitter

Submitter / Primary Contact Person	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
Secondary Contact Person	Alaine Medio Regulatory Affairs alaine.medio@siemens-healthineers.com +1 (240) 601-3848
Applicant Name and Address	Siemens Medical Solutions, Inc. USA 2501 North Barrington Road Hoffman Estates IL, 60192, USA Establishment Registration Number: 1423253

2. Device Name and Classification

Product Trace 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 Trace Name:	*syngo.*via MI Workflows; Scenium; syngo MBF
510(k) Number:	K211459
Clearance Date:	06/10/2021
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 Device

Trade Name:	*syngo.*via RT Image Suite
510(k) Number:	K220783
Clearance Date:	09/07/2022
Common Name:	Medical charged-particle radiation therapy system
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	MUJ

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 VB80A, Scenium with software version VE60, 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 VB80:

MI General

- Organ Segmentation and Organ Specific Tumor Burden
- Features from MM Oncology
  - Lesion Scout
  - PERCIST Reference Region
  - 3D VOI Iso-contour
- Minor Features
  - Consolidation of MI Workflows
  - 4D/4D Data in All Layouts
  - SSC Tools: Layout Editing and Reset Layout Tool
  - Color identification of timepoints

MM Onco

- CT Large Matrix Data Support
- Iodine Threshold
- Lesion Type Filter for *syngo.*CT Lung CAD
- Interactive Spectral Imaging

Scenium VE60:

- Tau workflow Support
- OpenApps Migration

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.

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Content of Premarket Submissions for Device Software Functions" issued on May, 2005 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.

Performance Testing

In addition to verification and validation testing, non-clinical performance evaluation was conducted in order to measure the accuracy of the deep-learning algorithm used for MI general organ segmentation, and to assess the agreement between the introduced tau quantification workflow against existing methods.

Clinical testing was not conducted for this submission.

Organ Segmentation

The organ segmentation consists of a region of interest detection based on anatomical landmarks, followed by a Deep Image-to-Image Network performing the actual segmentation step. The algorithm utilized is the same algorithm originally cleared within *syngo*.via RT Image Suite (K201444) and carried into the reference predicate device (*syngo*.via RT Image Suite, K220783).

The segmentation quality was assessed by comparing a manually annotated ground truth with the algorithm result using the overlap measure DICE coefficient and the average symmetric surface distance (ASSD: average surface distance between algorithm result and manual ground truth annotation). All organs met criteria for either the average DICE coefficient or the ASSD.

The following factors are known to affect the segmentation accuracy:

- Accuracy and calibration of the CT scanner used to acquire the images
- Image reconstruction settings, such as reconstruction kernel, slice thickness, spacing, resolution, and Field of View (FoV)
- If applicable, quantity of contrast media and injection protocol used
- Scan protocol used and dose delivered
- Patient compliance during image acquisition, for example, breathhold and motion
- Patient anatomy
- Organ size
- Patient orientation and position during image acquisition
- User skills

Tau Workflow Support

With the FDA approval of Tauvid (NDA 212123), also known as flortaucipir, a PET tracer that allows estimation of the distribution and density of tau protein in the brain, Siemens is implementing a workflow to support tau quantification in the MI Neuro Cortical Analysis workflow of Scenium.

Amyloid PET quantification has already been supported within the Cortical Analysis workflow of Scenium enabling the user to perform cortical SUVR calculations with respect to a reference region for the three FDA approved amyloid PET tracers.
Quantification steps of tau PET scans with the newly developed tau workflow are similar to the existing amyloid PET quantification, with a dedicated tau brain template for fusion to a standard space, and new cortical / background regions for SUVR calculations.

The (AAL) atlas[1], which is also utilized in the predicate device, was used as the basis to define all Braak regions in tau quantification workflow. Braak volumes of interest (VOIs) were all either existing in the AAL atlas or deduced from existing AAL regions.

SUVRs calculated on individual and composite Braak VOIs using our pipeline and our masks were compared to SUVRs calculated with an MR-based method and MR-based segmentations.[2]-[3] The comparisons showed good correlations and agreement between the two sets of values on more than 700 flortaucipir images from ADNI[4].

Risk Analysis

The risk analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

Standards

Siemens hereby certifies that *syngo.*CT Applications meets the following FDA Recognized Consensus standards listed below:

Recognition Number	Product Area	Title of Standard	Date of Recognition	Standards Development Organization
12-349	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set; PS 3.1 - 3.20 2022d	12/19/2022	NEMA
13-79	Software	Medical Device Software –Software Life Cycle Processes; 62304:2006 (1st Edition)/A1:2016	01/14/2019	AAMI, ANSI, IEC

[1] https://www.gin.cnrs.fr/en/tools/aal/
[2] R. Fahmi, "A PET only 18F-flortaucipir quantification: comparison with an MRI-based method", EANM'2021
[3] S. Landau et al., "Flortaucipir(AV-1451) processingmethods", ADNI publications, 2021
[4] https://adni.loni.usc.edu/

5-125	Software/ Informatics	Medical devices – Application of risk management to medical devices; 14971 Third Edition 2019-12	12/23/2019	ISO
5-129	General I (QS/RM)	Medical devices - Part 1: Application of usability engineering to medical devices 62366-1:2015+AMD1:2020	07/06/2020	AAMI, ANSI, IEC
5-134	General (QS/RM)	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements ISO 15223-1 Fourth edition 2021-07	12/20/2021	ISO

Conclusion

There are no differences in the Indications for Use, Intended Use, or Fundamental Technological Characteristics of the *syngo*.via MI Workflows VB80A software as compared to the currently commercially available *syngo*.via MI Workflows software (K211459).

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. Based on this information, as well as the documentation in support of the modifications, it is Siemens' opinion that the *syngo*.via MI Workflows software—with the modifications outlined in this application—is substantially equivalent to the predicate device.