July 19, 2019

Siemens Medical Solutions USA, Inc.
% Ms. Veronica Padharia
Regulatory Affairs Specialist
2501 N. Barrington Road
HOFFMAN ESTATES IL 60192

Re: K191309
Trade/Device Name: syngo.via MI Workflows VB40A, Scenium
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 17, 2019
Received: June 20, 2019

Dear Ms. Padharia:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: *06/30/2020*
See PRA Statement below.

510(k) Number *(if known)*
K191309

Device Name
syngo.via MI Workflows
VB40A, Scenium

Indications for Use *(Describe)*

***syngo*.via MI Workflows**

syngo.via MI Workflows are medical diagnostic applications for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR.
syngo.via MI Workflows enable visualization of information that would otherwise have to be visually compared disjointedly. *syngo*.via MI Workflows provide analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. *syngo*.via MI Workflows can perform harmonization of SUV (PET) across different PET systems or different reconstruction methods.
syngo.via MI workflows support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *syngo*.via MI Workflows are a complement to these standard procedures.

Scenium

The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.
The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDGPET, amyloid-PET, and SPECT studies, calculation of uptake ratios between regions of interest, and subtraction between two functional scans.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K191309

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

	Primary Contact:	*Alternate Contact:*
Submitter:	Veronica Padharia Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932	Clayton Ginn Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(630) 877–5761	(865) 898-2692
Fax Number:	(847) 304–6023	(865) 218-3019

Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Date of Submission:	May 13th 2019

Identification of the product

Device Proprietary Name:	*syngo*.via MI Workflows VB40A, Scenium
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II

Primary Predicate Device

Device Proprietary Name:	*syngo*.via MI Workflows VB30A
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II
Manufacturer:	Siemens Medical Solutions USA, inc.
510(k) Number:	K173897 (December 2017)

Reference Predicate Device

Device Proprietary Name:	Scenium VE20A
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	Class II
Manufacturer:	Siemens Medical Solutions USA, Inc.
510(k) Number:	K173597 (November 2017)

syngo.via MI Workflows VB30A is deemed the primary predicate device due to it being the most similar to the device under review of this submission with respect to indications for use and technical characteristics. Scenium VE30A is considered a reference device because it is a subset of the primary predicate device's indications for use and technical characteristics included within this submission.

Device Description

*syngo.*via MI Workflows is a software-only medical device which will be delivered on CD-ROM / DVD to be installed onto the commercially available Siemens *syngo.*via software platform (K191040) by trained service personnel.

*syngo.*via MI Workflows is a medical diagnostic application for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

*syngo.*via MI Workflows enable visualization of information that would otherwise have to be visually compared disjointedly. *syngo.*via MI Workflows provide analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. They additionally support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology (Oncology), Nuclear Medicine and Cardiology environments.

Scenium display and analysis software sits within the MI Neurology workflow within syngo.via MI Workflows. This software enables visualization and appropriate rendering of multimodality data, providing a number of features which enable the user to process acquired image data.

Scenium consists of four workflows:
- Database Comparison
- Striatal Analysis
- Cortical Analysis
- Subtraction

These workflows are used to assist the clinician with the visual evaluation, assessment and quantification of pathologies, such as dementia (i.e., Alzheimer's), movement disorders (i.e., Parkinson's) and seizure analysis (i.e., Epilepsy).

The modifications to the *syngo*.via MI Workflows and Scenium (MI Neurology) software (K173897 and K173597) include the following new features:

Workflow	Workflow-specific Features
MM Oncology	Interactive Trending
	Hybrid VRT / MIP ranges
	Spine and Rib labelling
MI Neurology (Scenium)	Factory Normals Database for DaTscan™
	Export Subtraction and Z-score Images as DICOM
	Z-score Image Overlay and Threshold Improvements
MI Reading / SPECT Processing	Renal Enhancements (extrapolation of T1/2)
	Integrate Image Registration Activity
MI Cardiology	*No updates / changes to third party applications within MI Cardiology or workflow functionality.*

Technological Characteristics

The *syngo*.via MI Workflows VB40A software modifications are based on the commercially

available *syngo*.via MI Workflows VB30A software (K173897) and Scenium VE20A (K173597). The features introduced into these Clinical Applications had no impact on the technological characteristics already present in the commercially available predicate system.

*syngo.*via MI Workflows is intended to be run on the Siemens *syngo*.via software platform (K191040) either alone or with other advanced commercially cleared applications.

Intended Use

An individual software program, or group of programs, routines, or algorithms that add specific image processing and/or analysis capabilities to a positron emission tomography (PET) and Single Photon Emission Computed Tomography (SPECT) imaging system configuration. A basic set of application programs and routines is included with such computer controlled imaging systems and they can be upgraded to correct programming errors or to add new system capabilities. Some application software routines or groups of routines (packages) must be combined with specific hardware or firmware accessories or configurations in order to function as intended. Application program packages are typically identified by a proprietary name and "version" or "upgrade" number.

The intended use for syngo.via MI Workflows is the same and, compared to the primary and reference devices, have not changed.

Indications for Use

syngo.via MI Workflows

syngo.via MI Workflows is a medical diagnostic application for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR.

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syngo.via MI workflows support the interpretation and evaluation of examinations and follow up documentation of findings within healthcare institutions, for example, in Radiology, Nuclear Medicine and Cardiology environments.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. syngo.via MI Workflows are a complement to these standard procedures.

Scenium, within the MI Neurology Workflow

The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.

The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDGPET, amyloid-PET, and SPECT studies, calculation of uptake ratios between regions of interest, and subtraction between two functional scans.

As stated above in the section describing predicate marketed devices, syngo.via MI Workflows VB30A is deemed the primary predicate device due to it being the most similar to the device under review of this submission with respect to indications for use and technical characteristics. Scenium VE30A is considered a reference predicate device because it is a subset of the primary predicate device's indications for use and technical characteristics.

Performance Testing / Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management has been ensured via risk analyses in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards for development including EN ISO 13485 and IEC 62304.

Cybersecurity information in accordance with FDA Guidance documents issued October 2, 2014 has been provided. The Clinical Applications software has specific cybersecurity controls to prevent unauthorized access, modifications, misuse or denial of use. Additionally, controls are enabled to prevent the unauthorized use of information that is stored, accessed or transferred between the Clinical Applications software and external devices.

Verification and Validation activities have been successfully performed on the software package, including assurance that functions work as designed, performance requirements and specifications have been met, and that all hazard mitigations have been fully implemented. All testing has met the predetermined acceptance values. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

The device is designed and manufactured in accordance with Quality System Regulations as outlined in 21 CFR 820. The FDA recognized standards are listed as follows:

- Recognition Number 13-79: IEC 62304 Edition 1.1 2015-06
- Recognition Number 12-300: NEMA PS 3.1 – 3.20 (2016)
- Recognition Number 5-40: ISO 14971:2007 Second Edition
- Recognition Number 5-114: IEC 62366-1 Edition 1.0 2015

- Recognition Number 5-117: ISO 15223-1 Third Edition 2016

Statement Regarding Substantial Equivalence:

There are no differences in the Indications for Use or Fundamental Technological Characteristics of the *syngo*.via MI Workflows software as compared to the currently commercially available software (K173897 and K173597). Both the current and predicate devices are used for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points

Additionally, there have been no changes that 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.