DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2016

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

Re: K160426
Trade/Device Name: syngo.via MI Workflows
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 10, 2016
Received: February 16, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160426

Device Name
syngo.via MI Workflows

Indications for Use *(Describe)*
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.

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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510(k) Summary

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

	Primary Contact:	*Alternate Contact:*
Submitter:	Veronica Padharia Regulatory Affairs Specialist Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 Barrington Road Hoffman Estates, IL 60192	M. Alaine Medio, RAC PET and PCS Regulatory Projects Manager Siemens Medical Solutions USA, Inc. Molecular Imaging 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(630) 877 – 5761	(865) 218 – 2703
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:	February 10, 2016

Identification of the product

Device Proprietary Name:	*syngo*.via MI Workflows – SPECT (Organ) Processing feature
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

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number	Type of Predicate
syngo.via MI Workflows VB10A	Siemens Medical Solutions USA, Inc	K151192 (June 2015)	Primary Predicate
MI Applications, Symbia 6.0	Siemens Medical Solutions USA, Inc	K142006 (July 2014)	Reference Predicate

Device Description

The SPECT Processing feature resides within *syngo*.via MI Workflows and is a software only medical device which will be delivered on CD-ROM / DVD to be installed onto the commercially available Siemens *syngo*.via MI Workflows software platform 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.

The modifications to the *syngo*.via MI Workflows (K151192) include the addition of the SPECT (Organ) Processing feature within the MI Reading workflow. This feature will integrate already existent functionality from Symbia 6.0, MI Applications (K142006) and provide the user additional organ-specific functionality for Nuclear Medicine (NM) and SPECT images within the *syngo*.SPECT Processing workflow.

Technological Characteristics

The *syngo*.via MI Workflows VB10B software modifications are based on the commercially available *syngo*.via VB10A software (K151192) as well as MI Applications software within Symbia 6.0 (K142006). The features introduced into *syngo*.via VB10B 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 (K150843) either alone or with other advanced commercially cleared applications.

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 14971:2012 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.

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 13-8: IEC 62304 First Edition 2006-05
- Recognition Number 12-238: NEMA PS 3.1 – 3.20 (2011)
- Recognition Number 5-40: ISO 14971 Second Edition 2007-03-01
- Recognition Number 5-95: IEC 62366-1 Edition 1.0 2015-02
- Recognition Number 5-90: ISO 15223-1 Second Edition 2012-07-01

Indications for Use

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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.

Statement Regarding Substantial Equivalence:

There are no differences in the Indications for Use or Fundamental Technological Characteristics of the *syngo*.via MI Workflows as compared to the currently commercially available software (K151192). Both 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.