Siemens Medical Solutions USA, Inc.
% Clayton Ginn
Regulatory Technical Specialist
2501 N Barrington Road
HOFFMAN ESTATES IL 60192

June 2, 2020

Re: K201202
Trade/Device Name: MI View&GO VA10A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 1, 2020
Received: May 4, 2020

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 (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,

For

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*

K201202

Device Name
MIView&GO VA10A

Indications for Use *(Describe)*

MI View&GO is a medical diagnostic application for viewing, manipulation, quantification, analysis and comparison of medical images with one or more time-points. MI View&GO supports 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).

MI View&GO is intended to be utilized by appropriately trained health care professionals to aid in the management of diseases associated with oncology, cardiology, neurology, and organ function. The images and results produced by MI View&GO can also be used by the physician to aid in radiotherapy treatment planning.

Type of Use *(Select one or both, as applicable)*

X 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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Section 05

510(k) Summary

K201202

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

	Primary Contact:	*Alternate Contact:*
Submitter:	Clayton Ginn Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932	Veronica Padharia Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 2501 N. Barrington Road Hoffman Estates, IL 60192
Telephone Number:	(865) 898-2692	(630) 877–5761
Fax Number:	(865) 218-3227	(847) 304–6023

Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA
Date of Submission:	May 1st, 2020

Identification of the product

Device Proprietary Name:	MI View&GO VA10A
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 VB40A
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:	K191309 (July 2019)

Reference Predicate Device

Device Proprietary Name:	syngo.CT View&GO VB20A
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:	K170952 (April 2017)

Reference Predicate Device

Device Proprietary Name:	syngo.CT Extended Functionality VB40A
Common Name:	Image Processing Software
Classification Name:	System, X-ray, Tomography, Computed per 21 CFR 892.1750

Product Code:	JAK
Classification Panel:	Radiology
Device Class:	Class II
Manufacturer:	Siemens Medical Solutions USA, Inc.
510(k) Number:	K192402 (September 2019)

syngo.via MI Workflows 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. syngo.CT View&GO and syngo.CT Extended Functionality are considered reference predicate devices because MI View&GO has integrated technical characteristics initially cleared within these devices.

Device Description

MI View&GO is a software-only medical device which will be delivered with the new generation of Siemens SPECT/CT and PET/CT scanners.

MI View&GO is a medical diagnostic application for viewing, manipulation, quantification, analysis and comparison of medical images with one or more time-points. MI View&GO supports 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)

MI View&GO is intended to be utilized by appropriately trained health care professionals to aid in the management of diseases associated with oncology, cardiology, neurology, and organ function.

MI View&GO includes the following features:

Feature	New Functionality	Modification Description
Auto Viewing	Yes	Stream data into the application immediately following acquisition.
Layout Gallery with Dynamic Summing, Automatic Layouts, and Remove Images	Yes	Generate Automatic Layouts at runtime, Automatically sum frames for review in the layout gallery, and remove images from a display
Configurable User Presets	Yes	Configuration UI for preferred presets and layouts
Tool Gallery	No	Functionality Cleared in K170952
Organ Processing	No	Functionality Cleared in K191309
MI Cardiology Reading and Third Party Software (Cedars 2017, Corridor 4DM 2018)	Yes	Restart applications and filter the cardiology data passed to an application.
Series Panel	No	Functionality Cleared in K170952, K191309
Basic Operation in the Viewer	Yes	Correct slice positions, panning, rotation on synchronized segments
Automatic Reconstruction, Auto Ranges, and Cardiac Auto Ranges	Yes	Generate parallel ranges with Auto Ranges and generate a series of images in cardiac planes Cardiac Auto Ranges
Display Types and Image Fusion	No	Functionality Cleared in K170952, K191309
3D Visualization and Orientation	No	Functionality Cleared in K170952, K191309
Restricting Volumes and Cardiac Masking	Yes	Mask the heart and exclude background regions that can have an impact on statistical calculations in an examination with Cardiac Masking.
Image Optimization and Preparation	No	Functionality Cleared in K170952, K191309
Toggle Image Overlay	Yes	Configure customized image text
Spine and Rib Labeling	No	Functionality Cleared in K191309

Neuro DSA	No	Functionality Cleared in K192402
Osteo Extension	No	Functionality Cleared in K192402
Oncology Extension	No	Functionality Cleared in K192402
Vessel Extension	No	Functionality Cleared in K192402
ROI HU Threshold	No	Functionality Cleared in K192402
Dual Energy ROI	No	Functionality Cleared in K192402
Endoscopic View	No	Functionality Cleared in K192402
Printing of Images	No	Functionality Cleared in K170952

Technological Characteristics

The MI View&GO software modifications are based on the commercially available *syngo*.via MI Workflows software (K191309), syngo.CT View&GO software (K170952), and syngo.CT Extended Functionality (K192402). The features introduced into this software device had no impact on the technological characteristics already present in the commercially available predicate system.

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 MI View&GO compared to the primary and reference device has not changed.

Indications for Use

MI View&GO is a medical diagnostic application for viewing, manipulation, quantification, analysis and comparison of medical images with one or more time-points. MI View&GO supports 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)

MI View&GO is intended to be utilized by appropriately trained health care professionals to aid in the management of diseases associated with oncology, cardiology, neurology, and organ function. The images and results produced by MI View&GO can also be used by the physician to aid in radiotherapy treatment planning.

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 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 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 Intended Use or Fundamental Technological Characteristics of the MI View&GO software as compared to the currently commercially available *syngo*.via MI Workflows software (K191309). The Indications for Use for MI View&GO is a condensed version of the Indications for Use of syngo.via MI Workflows and does not expand the intended use from that of the predicate device. 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 MI View&GO software—with the modifications outlined in this application—is substantially equivalent to the predicate device.