Siemens Medical Solutions USA, Inc.
% Clayton Ginn
Regulatory Affairs Specialist
810 Innovation Drive
KNOXVILLE TN 37932

August 19, 2022

Re: K222172
Trade/Device Name: MI View&GO
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: July 21, 2022
Received: July 21, 2022

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,

Julie Sullivan, 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

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.

510(k) Number *(if known)*

K222172

Device Name
MI View&GO

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)*

☒ 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

as required by 21 CFR Part 807.87(h)

Identification of the Submitter

	Primary Contact:	*Alternate Contact:*
Submitter:	Clayton Ginn Regulatory Affairs Professional Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932	Brian Wui Regulatory Affairs Professional Siemens Medical Solutions USA, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone Number:	(865) 898-2692	(865) 367-4337
Name / Address of Manufacturer	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA	
Date of Submission:	July 21st, 2022	

Identification of the product

Device Proprietary Name:	MI View&GO VA20A
Common Name:	Automated Radiological Image Processing Software
Classification Name:	Medical Image Management and Processing System per 21 CFR 892.2050
Product Code:	QIH
Classification Panel:	Radiology
Device Class:	Class II

Primary Predicate Device

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
Manufacturer:	Siemens Medical Solutions USA, inc.
510(k) Number:	K201202 (June 2020)

Reference Predicate Device

Device Proprietary Name:	*syngo*.via MI Workflows VB60A
Common Name:	Automated Radiological Image Processing Software
Classification Name:	Medical Image Management and Processing System per 21 CFR 892.2050
Product Code:	QIH, LLZ
Classification Panel:	Radiology
Device Class:	Class II
Manufacturer:	Siemens Medical Solutions USA, Inc.
510(k) Number:	K211459 (July 2021)

MI View&GO VA10A 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*.via MI Workflows VB60A is considered a reference predicate device because MI View&GO has integrated technical characteristics initially cleared within this device.

Device Description

MI View&GO is a software-only medical device which will be delivered in conjunction with Siemens SPECT/CT and PET/CT scanners. MI View&GO software provides additional specific capabilities for handling of PET and SPECT as well as CT and MR data directly at the acquisition console.

The MI View&GO software integrates molecular imaging more efficiently in the clinical environment by providing an interface for its users to review, post-process and read medical images immediately after acquisition. The purpose of the MI View&GO is to allow the technologist and reading physician to:

- Review acquired and reconstructed images at the scanner console
- Determine that the acquired data is of sufficient quality for reading, so the patient can be released.
- Prepare images for reading
- Perform a basic read

Modifications

The modification to the MI View&GO software that is the subject of this 510(k) Premarket Notification is the addition of the following features:

- Auto Lung 3D
- Gaussian Filter
- FAST Ranges Enhancements
- Automatic Layout Enhancements
- Open Apps
- Shared Software Component Tools and CT Plugins
  - Tools Export Tool
  - TimeCurve
  - Segmentation Tools
  - Synchronization Group Configuration
  - Oncology Extension Plugin
  - Interactive Spectral Imaging Plugin
  - Sim&GO Plugin
- Layout and User Interface Improvements:
  - 4D Support in All Layouts Including Volume Stripe
  - Dual Monitor Widescreen Layouts for Satellite Console
  - Gated Data Display
  - Customize Image Text in Volume Stripe
  - Default Windowing Updates
  - Remove Images from a MIP or VRT segment
  - Remove Blank Segments from Volume Stripe Layout
- Minor Usability Improvements:
  - Update to Organ Processing Tooltips
  - Default Presets and preservation upon upgrade

Technological Characteristics

The MI View&GO software modifications are based on the commercially available MI View&GO VA10A software (K201202) and *syngo*.via MI Workflows VB60A (K211459). The features introduced in MI View&GO VA20A do not alter the already existent technological characteristics within 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 predicate 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.

The MI View&GO VA20A Indications for Use is the same and, compared to the primary predicate device, has not changed.

Performance Testing / Safety and Effectiveness

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is included as part of this submission.

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.

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.

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

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.

The device is designed and manufactured in accordance with Quality System Regulations as outlined in 21 CFR 820.30.

The device meets the following recognized US FDA Consensus Standards:

FDA Recognition Number	Standard	Version	Content
13-79	IEC 62304	2006+A1: 2015	Medical Device Software - Software Life Cycle Processes
12-300	NEMA Standard PS 3.1-3.20	2016	Digital Imaging and Communications in Medicine (DICOM)
5-125	ISO 14971	2019	Application of Risk Management to Medical Devices
5-114	AAMI / ANSI / IEC 62366-1	2015	Application of usability engineering to medical devices
5-134	ISO 15223-1	2021	Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Statement Regarding Substantial Equivalence:

There are no differences in the Indications for Use, Intended Use, or Fundamental Technological Characteristics of the MI View&GO VA20A software as compared to the currently commercially available MI View&GO VA10A software (K201202).

Both the current and predicate devices are used for viewing, manipulation, quantification, analysis, and comparison of medical images 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 MI View&GO software—with the modifications outlined in this application—is substantially equivalent to the predicate device.