



August 30, 2024

Siemens Medical Solutions USA, Inc.  
Brian Wui  
Official Correspondent  
2501 North Barrington Road  
Hoffman Estates, Illinois 60192

Re: K242300

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: August 2, 2024  
Received: August 2, 2024

Dear Brian Wui:

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](mailto: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  
OHT8: Office of Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

k242300

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

### 1. Identification of the Submitter

<b>Submitter / Primary Contact Person</b>	Brian Wui Regulatory Affairs hansong.wui@siemens-healthineers.com +1 (865) 367-4337
<b>Secondary Contact Person</b>	Clayton Ginn Regulatory Affairs clayton.ginn@siemens-healthineers.com +1 (865) 898-2692
<b>Applicant Name and Address</b>	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:	MI View&GO VA30
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:	MI View&GO VA20
510(k) Number:	K201202
Clearance Date:	07/21/2022
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:	<i>syngo.via</i> MI Workflows VB80
510(k) Number:	K232000
Clearance Date:	11/28/2023
Common Name:	Medical image management and processing system
Classification Name:	Automated Radiological Image Processing Software
Classification Panel:	Radiology
CFR Section:	21 CFR §892.5050
Device Class:	Class II
Product Code:	QIH

## 4. 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

## 5. 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.

## 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

MI View&GO with software version VA30 software provides 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.

MI View&GO VA30:

- MI Features:
  - Brain AC-PC(Anterior Commissure – Posterior Commissure)
  - PERCIST
  - VOI Isocontour
- Shared Software Common Tools and CT Features:
  - Layout Editor
  - Average
  - Stroke Layout
- Layout Improvements:
  - MIP (Maximum Intensity Projection) Rotation
  - Volume Stripe Image Order

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

'Enhanced' software documentation per FDA's guidance document "Content of Premarket Submissions for Device Software Functions" issued on June, 2023 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 predetermined 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

The device under application, MI View&GO, did not conduct any additional performance testing.

### 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 predetermined 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 MI View&GO meets the following FDA Recognized Consensus standards listed below:

Designation Number and Edition/Date	Title	Standards Development Organization	Recognition Number
PS 3.1 - 3.20 2023e	Digital Imaging and Communications in Medicine (DICOM) Set	NEMA	12-349
62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical Device Software –Software Life Cycle Processes	AAMI, ANSI, IEC	13-79
14971 Third Edition 2019-12	Medical devices – Application of risk management to medical devices	ISO	5-125

62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices	AAMI, ANSI, IEC	5-129
15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	ISO	5-134
20417 First edition 2021-04 Corrected version 2021-12	Medical devices – Information to be supplied by the manufacturer	ISO	5-135

**Conclusion**

There are no differences in the Indications for Use, Intended Use, or Fundamental Technological Characteristics of the MI View&GO VA30 software as compared to the currently commercially available MI View&GO VA20 software (K222172).

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 MI View&GO software—with the modifications outlined in this application—is substantially equivalent to the predicate device.