November 20, 2025

Siemens Healthineers AG
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K253495
　　Trade/Device Name: syngo.MR Applications (VB80)
　　Regulation Number: 21 CFR 892.2050
　　Regulation Name: Medical image management and processing system
　　Regulatory Class: Class II
　　Product Code: LLZ, LNH
　　Dated: October 28, 2025
　　Received: October 28, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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) 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253495

Please provide the device trade name(s).

syngo.MR Applications (VB80)

Please provide your Indications for Use below.

syngo.MR Applications is a syngo based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

November 19, 2025

K253495

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. **Submitter:**
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3. **Device Name and Classification**

Device/Trade Name:	syngo.MR Applications (VB80)
Classification Panel:	Radiology Devices
Classification Number:	21 CFR 892.2050
Common Name:	System, Image Processing, Radiological
Classification Name:	Medical Image Management and Processing System
Device Class:	Class II
Product Code:	LLZ
Secondary Product Code(s):	LNH

4. **Predicate Device(s):**

Manufacturer	Predicate Device	510(k)
Siemens Healthineers AG	syngo.MR Applications VB40	K192462

5. Device Description:

syngo.MR Applications is a software only Medical Device consisting post-processing applications/workflows used for viewing and evaluating the designated images provided by a MR diagnostic device. The post-processing applications/workflows are integrated with the hosting application *syngo*.via, that enables structured evaluation of the corresponding images

6. Intended/Indications for use:

syngo.MR Applications is a syngo based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra.

7. Technological Characteristics:
The device syngo.MR Applications provides the below listed workflows.

- **MR General**
  syngo.MR General is a post-processing application for routine and advanced MR radiology usage. It supports basic routine MR reading and includes additional workflows for dedicated MR examinations that load and structure examination results automatically into meaningful layouts. syngo.MR General contains several MR Radiology workflows, Cardio-Vascular workflows and MR specific Evaluation features.
- **MR BreVis**
  syngo.MR BreVis is a post-processing software package for digital imaging that enables the skilled physician to perform real-time image analysis of dynamic MR datasets. Its purpose is to provide different reading and reporting capabilities to support the tumor diagnostic process for soft tissue.
- **MR Cardiology**
  syngo.MR Cardiology is a post-processing software application intended for viewing and analyzing cardiac magnetic resonance imaging (MRI) studies.
- **MR Neurology**
  syngo.MR Neurology is a post-processing software package, supporting convenient post-processing and reading of dynamic susceptibility contrast (DSC) perfusion MR imaging datasets.
- **MR Oncology**
  syngo.MR Oncology is a post-processing application, supporting convenient reading of MR scans of either multiple body regions or the entire body which have been acquired for clinical purposes such as oncological screening, staging, and grading.
- **MR Spectroscopy**
  syngo.MR Spectroscopy is used to determine the relative concentration of specific metabolites in the examined tissue of an MR spectroscopy scan.
- **MR Vascular**
  syngo.MR Vascular is a post-processing software application intended for viewing and analyzing magnetic resonance imaging (MRI) studies.
- **MR Prostate AI**
  Syngo.MR Prostate AI allows the user to read images of the prostate. With the lesion detection function, potential lesions can be segmented automatically.

  *Note: The subject device integrates the AI based Algorithm "**Prostate MR AI VA10A (K241770)**" without any modification. The algorithm is classified under a different regulation in its 510(K) and this is out-of-scope from the current submission of the subject device.*

8. Summary of Differences between the Subject Device and the Predicate Device:

The differences between the subject device described in this premarket notification and the predicate device are summarized in the following comparison table:

Specification	Subject Device	Predicate Device	Comparison
Device name and version	syngo.MR Applications (VB80)	syngo.MR Applications (VB40) K192462	New version of the predicate device with added features and enhancements
Product Classification	Product Code: LLZ Regulation Number: 892.2050	Product Code: LLZ Regulation Number: 892.2050	Same – The AI Algorithm "Prostate MR AI (K241770)" is developed as a stand-alone product and has its own development life cycle. It has its own classification, and it is not in scope of this submission
Indications for use	syngo.MR Applications is a syngo based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra	syngo.MR Applications is a syngo based post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-PET images and MR spectra	Same
Contraindications	syngo.MR is not to be used as a long term archiving device for patients' image data syngo.MR is not to be used as a sole basis for clinical decisions	syngo.MR is not to be used as a long term archiving device for patients' image data. syngo.MR is not to be used as a sole basis for clinical decisions.	Same
Software architecture	syngo.MR Applications has architecture that is based on a layered pattern where the various workflows are structured to provide their individual functionalities.	syngo.MR Applications has architecture that is based on a layered pattern where the various workflows are structured to provide their individual functionalities.	Same

Specification	Subject Device	Predicate Device	Comparison
Workflows	There are eight workflows. Each workflow functions independently with the same principle. It comprises of the following components: • *syngo*.MR General • *syngo*.MR Neurology • *syngo*.MR Cardiology • *syngo*.MR Oncology • *syngo*.MR Spectroscopy • *syngo*.MR Vascular • *syngo*.MR BreVis • ***syngo*.MR Prostate AI**	There areSeven workflows. Each workflow functions independently with the same principle. It comprises of the following components: • *syngo*.MR General • *syngo*.MR Neurology • *syngo*.MR Cardiology • *syngo*.MR Oncology • *syngo*.MR Spectroscopy • *syngo*.MR Vascular • *syngo*.MR BreVis	The new workflow MR Prostate AI enables the user to read Prostate images and detect lesions. The Minor enhancements were made to the existing workflows. - Findings assistant in MR Cardiology - Brain Morphometry in MR Neurology Common to all workflows - Common UI - Motion correction - ADC & b -value
Operating system	None Relies on the hosting application (syngo.via) for operating system.	None Relies on the hosting application (syngo.via) for operating system	Same
Clinical condition the device is intended to diagnose, treat, or manage	No limitation on the clinical condition of the patient	No limitation on the clinical condition of the patient	Same
Intended patient population	No limitation concerning the patient population (e.g., age, weight, health, condition)	No limitation concerning the patient population (e.g., age, weight, health, condition)	Same

Specification	Subject Device	Predicate Device	Comparison
Site of the body the device is intended to be used	No limitation concerning region of body or tissue type	No limitation concerning region of body or tissue type	Same
Intended user(s)	Trained healthcare professionals	Trained healthcare professionals	Same
Device Type	Software application	Software application	Same

9. Clinical Testing

No clinical studies were carried out for the product, all performance testing was conducted in a non-clinical fashion as part of verification and validation activities of the medical device

10. Bench Testing Evaluation Summary

No bench testing was required to be carried out for the product

11. Non-clinical Performance Testing:

Non-clinical tests were conducted for the subject device during product development. The modifications described in this Premarket Notification were supported with verification and validation testing.

Siemens Healthcare GmbH claims conformance to the following standards:

- ISO 14971 Third Edition 2019-12
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION
- IEC 82304-1 Edition 1.0 2016-10
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION

12. Software Verification and Validation:

Software documentation level of "Basic Documentation" per FDA's Guidance Document "Content of Premarket Submissions for Device Software Functions" is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the device Syngo.MR Applications during product development.

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 acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Siemens Healthcare GmbH conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Contained in this submission are our cybersecurity considerations as they relate to the device Syngo.MR Applications.

13. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device.

14. Conclusion as to Substantial Equivalence:

The predicate device was cleared based on non-clinical supportive information. The comparison of technological characteristics, device hazards, non-clinical performance data, and software validation data demonstrates that the subject device performs comparably to and is as safe and effective as the predicate device that is currently marketed for the same intended use.

In summary, we are of the opinion that the subject device Syngo.MR Applications, software version VB80, does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device Syngo.MR Applications VB40.