March 29, 2024

Siemens Medical Solutions USA, Inc.
Alina Goodman
Regulatory Affairs Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19355

Re: K240608
Trade/Device Name: MAGNETOM Viato.Mobile
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: February 29, 2024
Received: March 4, 2024

Dear Alina Goodman:

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240608

Device Name

MAGNETOM Viato.Mobile

Indications for Use *(Describe)*

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR § 807.92.

1. General Information

Establishment:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: February 29, 2024

Manufacturer:
Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany
Registration Number: 3002808157

2. Contact Information

Alina Goodman
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Phone: +1 (224) 526-1404
E-mail: alina.goodman@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name:	MAGNETOM Viato.Mobile
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

4. Legally Marketed Predicate Device

Trade name:	MAGNETOM Viato.Mobile
510(k) Number:	K232482
Clearance Date:	September 6, 2023
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: LNI, MOS

5. Intended Use / Indications for Use

The indications for use for the subject device is the same as the predicate device:

The MAGNETOM system is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM system may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room displays and MR Safe biopsy needles.

6. Device Description

MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system includes new hardware compared to the predicate device, MAGNETOM Viato.Mobile with software syngo MR XA51A and XJ gradient system. A high-level summary of the modified hardware is provided below:

Hardware

Modified Hardware

- Gradient Coil
- Gradient Power Amplifier

7. Substantial Equivalence

MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Viato.Mobile with syngo MR XA51A	K232482, cleared September 6, 2023	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system includes hardware already cleared on the following reference device:

Reference device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola Fit with software syngo MR XA51A Please note: the XQ gradient system, as part of MAGNETOM Sola Fit with software syngo MR XA51A, is the reference device related to modifications performed to provide a XQ gradient system option.	K221733, cleared December 13, 2022	LNH LNI, MOS	Siemens Healthcare GmbH

8. Comparison of technological Characteristics with the Predicate Device

The subject device, MAGNETOM Viato.Mobile with software syngo MR XA51A, and XQ gradient system is substantially equivalent to the predicate device with regard to the intended use, operational environment, programming language, operating system and performance.

The subject device conforms to the standard for medical device software (IEC 62304) and other relevant IEC and NEMA standards.

There are no differences in technological characteristics between the subject device and predicate device, but new hardware, these differences have been tested and the conclusion from the non-clinical data suggests that the system bears an equivalent safety and performance profile to that of the predicate device.

9. Nonclinical Tests

The following performance testing was conducted on the subject device.

Performance Test	Tested Hardware or Software	Source/Rationale for test
Performance bench test	new hardware	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

Verification and validation	new hardware	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Electrical safety and electromagnetic compatibility (EMC)	complete system	IEC 60601-1-2

The results from each set of tests demonstrate that the subject device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

10. Clinical Tests / Publications

No clinical study and no additional clinical tests were conducted to support substantial equivalence for the subject device.

11. Safety and Effectiveness

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

Risk management is ensured via a risk analysis in compliance with ISO 14971, to identify and provide mitigation of potential hazards early in the design cycle and continuously throughout the development of the product. Siemens Healthcare GmbH adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system conforms to the following FDA recognized and international IEC, ISO and NEMA standards:

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General II (ES/ EMC)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	ANSI AAMI

19-8	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2, Ed. 4.0:2014	IEC
12-295	Radiology	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	60601-2-33, Ed. 3.2:2015	IEC
5-125	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Third Edition 2019-12	ISO
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA

12. Conclusion as to Substantial Equivalence

MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Viato.Mobile with syngo MR XA51A and XJ gradient system, with respect to the magnetic resonance features and functionalities. There are no differences in technical features compared to the predicate device, but new hardware. The resulting differences have been tested and the conclusions from all verification and validation data suggest that the system bears an equivalent safety and performance profile to that of the predicate device and reference device.

Siemens believes that MAGNETOM Viato.Mobile with software syngo MR XA51A and XQ gradient system is substantially equivalent to the currently marketed device MAGNETOM Viato.Mobile with software syngo MR XA51A and XJ gradient system(K232482, cleared on September 6, 2023).