



September 6, 2023

Siemens Medical Solutions USA, Inc.  
% Alina Goodman  
Regulatory Affairs Professional  
40 Liberty Boulevard  
MALVERN PA 19355

Re: K232482

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: August 15, 2023  
Received: August 16, 2023

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 (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a faint, light blue watermark of the FDA logo.

Daniel M. Krainak, Ph.D.  
Assistant Director  
Magnetic Resonance and Nuclear Medicine Team  
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)

K232482

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:** August 15, 2023

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

## 2. Contact Information

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Regulatory Affairs Professional  
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## 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 Sola Fit  
**510(k) Number:** K221733  
**Clearance Date:** December 13, 2022  
**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 includes minor modified hardware compared to the predicate device, MAGNETOM Sola Fit with software syngo MR XA51A. A high level summary of the modified hardware is provided below:

##### **Hardware**

##### **Modified Hardware**

- Cover

##### **Other Modifications and / or Minor Changes**

- Adaptations for installation in a mobile trailer

- MAGNETOM Viato.Mobile is a mobile MR system which enables the customers to relocate the MRI system to different locations and therefore provide imaging services where it is needed.

## 7. Substantial Equivalence

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

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sola Fit with syngo MR XA51A	K221733, cleared December 13, 2022	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Viato.Mobile with software syngo MR XA51A includes hardware already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Aera with software syngo MR XA30A  Please note: the Mobile Solution, as part of MAGNETOM Aera with software syngo MR XA30A, is the reference device related to modifications performed to fit the subject device to the mobile environment.	K202014, cleared September 8, 2020	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Avanto Fit with software syngo MR XA50A  Please note: reference device related to the cover	K220151, cleared April 1, 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, is substantially equivalent to the predicate device with regard to the 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 minor modified hardware and an installation in a mobile trailer, 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	modified hardware	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Verification and validation	modified 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 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
5-114	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]	62366-1 Edition 1.0 2015-02	IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC
2-258	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process	10993-1 Fifth edition 2018-08	ISO
12-342	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 2021e	NEMA
12-188	Radiology	Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images	MS 1:2008 (R2020)	NEMA
12-196	Radiology	Determination of Two-dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images	MS 2:2008 (R2020)	NEMA



12-187	Radiology	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images	MS 3:2008 (R2020)	NEMA
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-322	Radiology	Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging	MS 5:2018	NEMA
12-195	Radiology	Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)	MS 6:2008 (R2014)	NEMA
12-315	Radiology	Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems	MS 8:2016	NEMA
12-288	Radiology	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	MS 9-2008 (R2020)	NEMA
12-298	Radiology	Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging Systems	MS 10 - 2010	NEMA
12-306	Radiology	Quantification and Mapping of Geometric Distortion for Special Applications	MS 12 - 2016	NEMA

## 12. Conclusion as to Substantial Equivalence

MAGNETOM Viato.Mobile with software syngo MR XA51A has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Sola Fit with syngo MR XA51A, with respect to the magnetic resonance features and functionalities. There are no differences in technical features compared to the predicate device, but minor modified hardware and an installation in a mobile trailer. 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 devices.

Siemens believes that MAGNETOM Viato.Mobile with software syngo MR XA51A is substantially equivalent to the currently marketed device MAGNETOM Sola Fit with software syngo MR XA51A (K221733, cleared on December 13, 2022).