November 14, 2023

Siemens Medical Solutions USA, Inc.
Milind Dhamankar
Clinical Affairs Professional
40 Liberty Boulevard
Malvern, PA 19355

Re: K232494
Trade/Device Name: MAGNETOM Avanto^{fit}; MAGNETOM Skyra^{fit}
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: August 13, 2023
Received: August 17, 2023

Dear Milind Dhamankar:

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232494

Device Name

MAGNETOM Avanto fit;
MAGNETOM Skyra fit

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.

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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 08, 2023

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

2. Contact Information

Milind Dhamankar
Clinical Affairs Professional
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3. Device Name and Classification

Device/ Trade name:	MAGNETOM Avanto^{fit} MAGNETOM Skyra^{fit}
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 and Reference Device

4.1. Predicate Device for MAGNETOM Skyra^{fit}

Trade name:	MAGNETOM Vida
510(k) Number:	K213693
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

4.2. Predicate Device for MAGNETOM Avanto^{fit}

Trade name:	MAGNETOM Sola
510(k) Number:	K221733
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

4.3. Reference Device for MAGNETOM Skyra^{fit}

Trade name:	MAGNETOM Skyra^{fit}
510(k) Number:	K162102
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

4.4. Reference Device for MAGNETOM Avanto^{fit}

Trade name:	MAGNETOM Avanto^{fit}
510(k) Number:	K162102
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. Intended Use / Indications for Use

The indications for use for the subject devices are 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.

5. Device Description

The subject devices, MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A, consist of new and modified software and hardware that is similar to what is currently offered on the predicate device, MAGNETOM Sola with *syngo* MR XA51A (K221733) and MAGNETOM Vida with syngo MR XA50A (K213693).

A high-level summary of the new and modified hardware and software is provided below:

MAGNETOM Avanto^{fit} with *syngo* MR XA61A:

Hardware

New Hardware:

- Flex Loop Large
- UltraFlex Large 18
- UltraFlex Small 18
- Contour 24

Modified Hardware:

- Host computers ((syngo MR Acquisition Workplace (MRAWP) and syngo MR Workplace (MRWP))

Software

New Features and Applications:

- GRE_PC
- Physiologging
- Open Recon Framework

Modified Features and Applications:

- BEAT_nav (re-naming only)

MAGNETOM Skyra^{fit} with *syngo* MR XA61A:

Hardware

New Hardware:

- UltraFlex Large 18
- UltraFlex Small 18
- Contour 24

Modified Hardware:

- Host computers ((syngo MR Acquisition Workplace (MRAWP) and syngo MR Workplace (MRWP))
- MaRS (Measurement and Reconstruction System) computer

New Features and Applications:

- GRE_PC
- Physiologging
- Open Recon Framework

Modified Features and Applications:

- BEAT_nav (re-naming only)
- myExam Angio Advanced Assist (Test Bolus)

6. Substantial Equivalence

MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A is substantially equivalent to the following predicate device:

Predicate Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Sola with *syngo* MR XA51A	K221733 on September 13, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Vida with *syngo* MR XA50A	K213693 on February 25, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH
Reference Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Avanto^{fit} with *syngo* MR VE11E	K162102 on November 22, 2016	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Skyra^{fit} with *syngo* MR VE11E	K162102 on November 22, 2016	LNH, LNI, MOS	Siemens Healthcare GmbH

7. Technological Characteristics

The subject devices, MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A, are substantially equivalent to the predicate devices with regard to the operational environment, programming language, operating system and performance.

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

There are some differences in technological characteristics between the subject device and predicate device, including new and modified hardware/software. Here is summary of differences:

Summary hardware comparison table for the subject and predicate/reference device

Hardware	**Subject Devices** MAGNETOM Avanto^{fit} MAGNETOM Skyra^{fit} with software *syngo* MR XA61A	**Predicate Device** MAGNETOM Vida with *syngo* MR XA50A (K213693) MAGNETOM Sola with syngo MR XA51A (K221733)	**Reference Devices** MAGNETOM Avanto^{fit} MAGNETOM Skyra^{fit} with *syngo* MR VE11E[1] (K162102)
Magnet System	Yes	Yes	Yes
RF System	Yes	Yes	Yes
Transmission technique	Yes	Yes	Yes
Gradient System	Yes	Yes	Yes
Patient Table	Yes	Yes	Yes
Multi-Nuclear Option - Supported Nuclei	Yes Only for MAGNETOM Skyra^{fit}	Yes Only for MAGNETOM Vida	Yes Only for MAGNETOM Skyra^{fit}
Computer	Yes Modified compared to predicate device: - New MRAWP and MRWP - New MaRS hardware for MAGNETOM Skyra^{fit}	Yes	Yes
Coils	Yes, new coils - Flex Loop Large (only for MAGNETOM Avanto^{fit}) - UltraFlex Large 18 - UltraFlex Small 18 - Contour 24/48[2]	Yes	Yes
Other HW components	Yes	Yes	Yes

Summary software comparison table for the subject and predicate devices

Software	**Subject Devices** MAGNETOM Avanto^{fit} MAGNETOM Skyra^{fit} with software *syngo* MR XA61A	**Predicate Device** MAGNETOM Vida with *syngo* MR XA50A (K213693)

[1] Change released by internal documentation based on MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with syngo MR E11C (K162102)

2 Contour 24 (K183111, cleared on December 7, 2018 and K173446, was cleared November 17, 2017)

		MAGNETOM Sola with syngo MR XA51A (K221733)
Sequences		
SE-based pulse sequence types	Yes	Yes
GRE-based/Steady-State pulse sequence types	New or modified pulse sequences: - GRE_PC new pulse sequence - BEAT_NAV pulse sequence re-naming	Yes
EPI-based pulse sequence types	New features: - Physiologging for EPI2D_BOLD and EPI2D_PACE	Yes
Spectroscopy pulse sequence types	Yes	Yes
Feature and Applications		
Other features and applications such as: -Application Suites -myExam Assists -Other Imaging Applications	Modified application feature: - myExam Angio Assist (Test Bolus and Care bolus) for MAGNETOM Skyra^{fit}	Yes
User interface and user interaction	Yes	Yes
Viewing and post-processing	Yes	Yes
Workflow and software utilization	Yes	Yes
Patient Management	Yes	Yes
Scan Modes and Pulse Sequences	Yes	Yes
Scanning	Yes	Yes
Reconstruction	New feature: - OpenRecon Framework	Yes
Image Display	Yes	Yes
File/Data Management	Yes	Yes

The differences have been tested and the conclusion from the non-clinical data suggests that the features bear an equivalent safety and performance profile to that of the predicate device.

8. Nonclinical Tests

The following **performance testing** was conducted on the subject devices:

Performance Test	**Tested Hardware or Software**	**Source/Rationale for test**
Software verification and validation	New or modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Sample clinical images	New or modified software features and coils	Guidance for submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessment by sample clinical images	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	

Physiologging Verification Report	Physiologging	New Feature Introduction

The following **performance testing for local coils** was conducted on the predicate and the reference devices and can be reused for the subject devices:

Performance Test	Tested Hardware or Software	Source/Rationale for test
Performance bench test	- SNR and image uniformity measurements for coils - Heating measurements for coils	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

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

9. Clinical Tests / Publications

No clinical tests were conducted to support substantial equivalence for the subject devices; however, as stated above, sample clinical images were provided.

Furthermore, additional clinical publications were referenced to provide information on the use of the following features and functions:

Feature	Publications
GRE_PC	[1] Guenthner C. et al. Ristretto MRE: A generalized multi-shot GRE-MRE sequence. NMR Biomed 2019; 32:e4049.

10. 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 Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A 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	Medical electrical equipment - part 1: general requirements for basic safety and essential performance	ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012	AAMI / ANSI
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 Edition 4.0:2014-02	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 b:2015	IEC
5-125	General	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	62366-1:2015	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	IEC
12-195	Radiology	NEMA MS 6-2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	MS 6-2008 (R2014)	NEMA
12-342	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20 (2021e)	NEMA
2-258	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1 Fifth edition 2018-08	AAMI ANSI ISO

11. Conclusion as to Substantial Equivalence

MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A have the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA50A and MAGNETOM Sola with *syngo* MR XA51A, with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate device, the differences have been tested and the

conclusions from all verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device and reference devices.

Siemens believes that MAGNETOM Avanto^{fit} and MAGNETOM Skyra^{fit} with software *syngo* MR XA61A are substantially equivalent to the currently marketed devices MAGNETOM Vida with software *syngo* MR XA50A (K213693, cleared on February 25, 2022) and MAGNETOM Sola with *syngo* MR XA51A (K221733 on September 13, 2022).