Siemens Medical Solutions USA, Inc.
℅ Martin Rajchel
Senior Regulatory Affairs Manager
40 Liberty Boulevard, Mail Code 65-1A
MALVERN PA 19355

May 13, 2022

Re: K220589
Trade/Device Name: 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: February 25, 2022
Received: March 1, 2022

Dear Martin Rajchel:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Thalia T. Mills, Ph.D.
Director
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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.

510(k) Number *(if known)*

K220589

Device Name
MAGNETOM Skyra Fit

Indications for Use *(Describe)*

Your 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.

Your 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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: May 3, 2022

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

2. Contact Information

Martin Rajchel
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3. Device Name and Classification

Device/ Trade name:	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 Device

Trade name:	MAGNETOM Vida
510(k) Number:	K203443
Clearance Date:	March 31, 2021
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

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

Your 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.

Your 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 Skyra Fit with software *syngo* MR XA50A includes new and modified hardware and software compared to the predicate device, MAGNETOM Vida with software *syngo* MR XA31A. A high level summary of the new and modified hardware and software is provided below:

Hardware
Modified Hardware

- **Cover:** The cover has been modified to bring the system up to the Siemens Healthineers Design incl. all BioMatrix components and interfaces.
- **EPC** (Electronic Cabinet and Measurement Control / Electronic Power Cabinet): upgrade of components to upgrade the EPC to the newest electronic cabinet series

Software
New Features and Applications
- **TSE MoCo**: TSE MoCo is an image-based motion correction in the average-dimension for the TSE pulse sequence type.
- **Automatic fiducial detection**: MR Breast Biopsy is improved with an automatic fiducial detection.

Modified Features and Applications
- **Fast GRE RefScan**: A speed-optimized reference scan for GRAPPA and SMS kernel calibration for echo planar imaging pulse sequence types.

Other Modifications and / or Minor Changes
- The **MAGNETOM Skyra Fit** is a new MRI System which is the result of an upgrade from a MAGNETOM Verio.

7. Substantial Equivalence

MAGNETOM Skyra Fit with software *syngo* MR XA50A is substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA31A	K203443, cleared March 31, 2021	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Skyra Fit with software *syngo* MR XA50A includes hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Verio with software *syngo* MR E11D	K181613, cleared November 6, 2018	LNH LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Skyra^{fit} with software *syngo* MR E11C-AP04	K173592, cleared February 13, 2018	LNH LNI, MOS	Siemens Healthcare GmbH

8. Comparison of technological Characteristics with the Predicate Device

The subject device, MAGNETOM Skyra Fit with software *syngo* MR XA50A, 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.

While there are some differences in technological characteristics between the subject device and predicate device, including new and modified hardware and software, these differences have been tested and the conclusions from the non-

clinical data suggests that the features bear 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
Sample clinical images	coils, new and modified software features	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Image quality assessments by sample clinical images. In some cases a comparison of the image quality / quantitative data was made.	- new / modified pulse sequence types. - comparison images between the new / modified features and the predicate device features	
Performance bench test	new and modified hardware	
Software verification and validation	new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Electrical, mechanical, structural, and related system safety test	complete system	- AAMI / ANSI ES60601-1 - IEC 60601-2-33

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

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 Skyra Fit with software *syngo* MR XA50A 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
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
5-40	General I (QS/ RM)	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	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
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1 - 3.20:2016	NEMA

12. Conclusion as to Substantial Equivalence

MAGNETOM Skyra Fit with software *syngo* MR XA50A has the same intended use and same basic technological characteristics than the predicate device system, MAGNETOM Vida with *syngo* MR XA31A, 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 Skyra Fit with software *syngo* MR XA50A is substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA31A (K203443, cleared on March 31, 2021).