Siemens Medical Solutions USA, Inc.
℅ Mr. Andrew Turner
Regulatory Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

September 8, 2020

Re: K202014
Trade/Device Name: MAGNETOM Aera, MAGNETOM Skyra, Magnetom Prisma/Prisma^{fit} with syngo MR XA30A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: July 17, 2020
Received: July 21, 2020

Dear Mr. Turner:

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
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K202014

Device Name

MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma/Prisma Fit with syngo MR XA30A

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 display 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
Mail Code 65-1A
Malvern, PA 19355, USA
Registration Number: 2240869

Date Prepared: July 17, 2020

Manufacturer:

Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen
Germany
Registration Number: 3002808157
Siemens Shenzhen Magnetic Resonance LTD.
Siemens MRI Center
Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Registration Number: 3004754211

2. Contact Information

Andrew Turner,
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
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Malvern, PA 19355, USA
Phone: (610) 850-5627
Fax: (610) 448-1787
E-mail:

3. Device Name and Classification

Device/Trade name:	MAGNETOM Aera, MAGNETOM Skyra, MAGNETOM Prisma/ Prisma^{fit} with *syngo* SW XA30A
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:	K192924
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 devices are 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 Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A, include new and modified hardware and software compared to the predicate device, MAGNETOM Vida with software *syngo* MR XA20A. A high-level summary of the new and modified hardware and software is provided below:

Hardware

- New Computer

Software

New Features and Applications

- **SVS_EDIT** is a special variant of the SVS_SE pulse sequence type, which acquires two different spectra (one with editing pulses on resonance, one with editing pulses off resonance) within a single sequence.
- **BEAT_FQ_nav** is a pulse sequence that allows the user to make use of navigator echo based respiratory gating for flow imaging to acquire 4D flow data. Both navigator echo based respiratory gating and flow imaging are cleared features available on the predicate device. However, the combination of the two is new.
- **Injector coupling** is a software application that allows the connection of certain contrast agent injectors to the MR system for simplified, synchronized contrast injection and examination start.
- The **Prostate Dot Engine** provides an assisted and guided workflow for prostate imaging. This automated workflow leads to higher reproducibility of slice angulation and coverage based on the segmentation algorithm described and cleared with syngo.via VB40; this may support exams not having to be repeated.

Modified Features and Applications

- An optimized **high bandwidth inversion recovery** pulse is combined with gradient echo readout to improve diagnostic image quality when imaging myocardial tissue.
- The **AbsoluteShim** mode is a shimming procedure based on a 3-echo gradient echo protocol.

Other Modifications and / or Minor Changes

- **Elastography-AddIn** synchronizes settings between the Elastography sequence and the active driver.
- **HASTE MoCo** is an image-based motion correction function in the average-dimension for the HASTE pulse sequence type.
- **Coil independent pulse sequences** remove the coil information from the pulse sequences and generate this information during run-time from automatic coil detection and localization.

7. Substantial Equivalence

MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A are substantially equivalent to the following predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Vida with *syngo* MR XA20A	K192924, cleared March 11, 2020	LNH LNI, MOS	Siemens Healthcare GmbH

MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A include hardware and software already cleared on the following reference devices:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR VE11C	K153343, cleared April 15, 2016	LNH LNI, MOS	Siemens AG / Siemens Healthcare GmbH
*syngo.*via VB40	K192462, Cleared January 31, 2020	LLZ, LNH	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A, are substantially equivalent to the predicate device 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.

As seen above there are some differences in technological characteristics between the subject devices and predicate device, including different hardware and modified 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 devices.

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 using sample clinical images. In some cases, a comparison of the image quality / quantitative data was made.	- new / modified pulse sequence types and algorithms. - 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

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

10. 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. Clinical publications were referenced to provide information on the use of the following features and functions.

Feature / Function	Clinical Publication
SVS_EDIT	[1] Mescher et al, Simultaneous in vivo spectral editing and water suppression, NMR Biomed 11, 266–272 (1998)
	[2] Mikkelsen et al, Big GABA: Edited MR spectroscopy at 24 research sites, NeuroImage 159, 32–45 (2017)
	[3] Saleh et al, Multi-vendor standardized sequence for edited magnetic resonance spectroscopy, NeuroImage 189, 425–431 (2019)
Prostate Dot Engine	[7] Essner M, Zinsser D, Kündel M, et. al. Performance of an Automated Workflow for Magnetic Resonance Imaging of the Prostate: Comparison With a Manual Workflow. Invest Radiol. 2020 May;55(5):277-284. Doi: 10.1097.
	[8] Horger W, Thoermer G, Weiland E, et. al. Prostate Dot Engine – a system guided and assisted workflow to improve consistency in prostate MR exams.
	[9] Yadong C, Siyuan H, Chunmei Li, et. al. Performance and Reproducibility of a Day Optimizing Throughput (Dot) Workflow Engine in Automated Prostate MRI Positioning. Abstract accepted for the 28th annual meeting of the International Society of Magnetic Resonance in Medicine (ISMRM).

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 Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A conform 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	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
5-40	General	Medical devices - Application of risk management to medical devices	14971: 2007	ISO
5-114	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC

13-79	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	AAMI ANSI IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4:2010	NEMA
12-288	Radiology	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)	MS 9:2008	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA
2-220	Biocompatibility	biological evaluation of medical devices - part 1: evaluation and testing within a risk management process (Biocompatibility)	10993-1: 2009	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A have the same intended use and same basic technological characteristics as the predicate device system, MAGNETOM Vida with *syngo* MR XA20A, 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 Aera, MAGNETOM Skyra and MAGNETOM Prisma/ Prisma^{fit} with software *syngo* MR XA30A are substantially equivalent to the currently marketed device MAGNETOM Vida with software *syngo* MR XA20A (K192924, cleared on March 11, 2020).