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

June 24, 2022

Re: K220575
Trade/Device Name: MAGNETOM Free.Max with syngo MR XA50A and MAGNETOM Free.Star with syngo MR XA50A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: May 25, 2022
Received: May 26, 2022

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

Sincerely,

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: 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)*
K220575

Device Name
MAGNETOM Free.Max with syngo MR XA50A and MAGNETOM Free.Star with syngo MR XA50A

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

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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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: June 22, 2022

Manufacturer:
Siemens Shenzhen Magnetic Resonance Ltd.
Siemens MRI Center, Gaoxin C. Ave., 2nd
Hi-Tech Industrial Park
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA
Registration Number: 3004754211

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
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E-mail: alina.goodman@siemens-healthineers.com

3. Device Name and Classification

Device/ Trade name: MAGNETOM Free.Max with *syngo* MR XA50A
MAGNETOM Free.Star with *syngo* MR XA50A
Classification Name: Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel: Radiology
CFR Code: 21 CFR § 892.1000
Classification: II
Product Code: Primary: LNH
Secondary: MOS

4. Legally Marketed Predicate Device

Trade name:	MAGNETOM Free.Max
510(k) Number:	K210611
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: MOS

5. Intended Use

The MAGNETOM MR system is indicated for use as a magnetic resonance diagnostic device (MRDD), which produces transverse, sagittal, coronal, and oblique cross sectional images that display the internal structure and/or function of the head, body, or extremities. Other physical parameters derived from the images may also be produced. Depending on the region of interest, contrast agents may be used.

These images and the physical parameters derived from the images when interpreted by a trained physician yield information that may assist in diagnosis.

6. Device Description

The subject device software version, *syngo* MR XA50A, can support the following two MRI systems:

- MAGNETOM Free.Max, which has been cleared with its initial software version *syngo* MR XA40A, through K210611 on July 1, 2021;
- MAGNETOM Free.Star, a new product.

With the introduction of MAGNETOM Free.Star, we extend the Free. platform, which consists of two products with a field strength of 0.55 Tesla on our high-value MRI platform. The main difference between these two products is the bore size, MAGNETOM Free.Star is equipped with a 60 cm patient bore while the MAGNETOM Free.Max is equipped with an 80 cm patient bore. The Gradient system, body coil and the system cover for MAGNETOM Free.Star are modified based those of the predicate device MAGNETOM Free.Max with syngo MR XA40A (K210611) to accommodate the smaller bore diameter. The other main components for the new device MAGNETOM Free.Star are the same as those of MAGNETOM Free.Max as cleared with K210611.

Apart from the hardware adaption applied for MAGNETOM Free.Star for the smaller bore diameter, the new / modified hardware and software features for the subject devices comparing to the predicate device MAGNETOM Free.Max with software version syngo MR XA40A (K210611, cleared on July 1, 2021) are listed below:

<table>
<tr><th>MAGNETOM Free.Max</th><th>MAGNETOM Free.Star</th></tr>
<tr><th colspan="2">software version syngo MR XA50A</th></tr>
<tr><td colspan="2">New/Modified Hardware</td></tr>
<tr><td colspan="2">Common for both subject devices:</td></tr>
<tr><td colspan="2">

Scanner User Interface (SUI): introduce option to have two SUI set on both sides of the scanner, while there is only one set available on the left hand side as the standard configuration for the predicate device MAGNETOM Free.Max with software version syngo MR XA40A (K210611); Swap the orientation of patient pictogram on Select&GO is supported syngo MR XA50A.
myExam 3D Camera: auto registration with detection of patient height, weight and orientation are supported in the subject device software version syngo MR XA50A. The hardware remains unchanged as cleared with K210611 on July 1, 2021.
New Patient Video: A new patient video with 1920×1080 pixels is introduced.

</td></tr>
<tr><td colspan="2">Applicable to the following subject device(s)</td></tr>
<tr><td>MAGNETOM Free.Max</td><td>MAGNETOM Free.Star</td></tr>
<tr><td colspan="2">New Local Coils</td></tr>
<tr><td>Contour M Coil</td><td>Contour M Coil</td></tr>
<tr><td>New Patient table –
High-load patient table: a new fixed patient table with vertical movement for heavy load patient is introduced.</td><td>N/A</td></tr>
<tr><td colspan="2">Software Features</td></tr>
<tr><td colspan="2">Common for both subject devices:</td></tr>
<tr><td colspan="2">
<u>New Software Platform/Workflow</u>
myExam Autopilot is extended the supporting body region to shoulder:

myExam Shoulder Autopilot: it helps users to automate a shoulder examination.

<u>Migrated Software feature</u>

EP2D_FID: Single-shot FID EPI pulse sequence type optimized for perfusion-imaging in the brain.
Inline Perfusion: Automatic real-time calculation of parameter maps with Inline technology based on image data acquired with the ep2d_fid pulse sequence type.
Access-i: Provides an interface to enable the connection of a 3rd party workstation to the MR syngo Acquisition Workplace via a network router and secure local network connection.

<u>Modified Software Platform/Workflow</u>
Modify in Scan assistance: Modified guidance of off-center imaging is provided to users who encounter the scan suspension by too off-centered shim volume.
</td></tr>
</table>

7. Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA50A are substantially equivalent to the predicate device and includes migrated features from the following reference devices:

Predicate Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Free.Max with *syngo* MR XA40A	K210611, cleared on July 1, 2021	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
Reference Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Sola with *syngo* MR XA20A	K192496, cleared on February 28, 2020	LNH, LNI, MOS	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA50A, 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.

There are some differences in technological characteristics between the subject devices and predicate device, including 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 devices.

Performance Test	**Tested Hardware or Software**	**Source/Rationale for test**
Sample clinical images	Coils, new and modified software features, pulse sequence types	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Performance bench test	- SNR and image uniformity measurements for coils - Heating measurements for coils	
Software verification and validation	mainly 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 thus 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 device; however, as stated above, sample clinical images were provided.

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 adheres to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards. Furthermore, the devices are intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA50A 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 II (ES/ EMC)	C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) 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	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 b: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	62366-1:2015	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	62304:2006/A1:2016	ANSI AAMI IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	NEMA

12-288	Radiology	Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	MS 9-2008 (R2014)	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA
2-258	Biocompatibility	biological evaluation of medical devices - part 1: evaluation and testing within a risk management process (Biocompatibility)	10993-1:2018	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA50A have the same intended use and same basic technological characteristics as the predicate device system, MAGNETOM Free.Max with *syngo* MR XA40A (Cleared with K210611 on July 1, 2021), 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 device.

Siemens believes that MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA50A are substantially equivalent to the currently marketed device MAGNETOM Free.Max with *syngo* MR XA40A.