Siemens Medical Solutions USA, Inc.
Alina Goodman
Regulatory Affairs Professional
40 Liberty Boulevard
Malvern, Pennsylvania 19355

November 9, 2023

Re: K231617
Trade/Device Name: MAGNETOM Free.Max; MAGNETOM Free.Star
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: September 11, 2023
Received: September 11, 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 (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,

Julie Sullivan -S

Julie Sullivan, Ph.D.
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)*

K231617

Device Name

MAGNETOM Free.Max;
MAGNETOM Free.Star

Indications for Use *(Describe)*

MAGNETOM Free.Max:
MAGNETOM Free.Max system is indicated for use as a magnetic resonance diagnostic device (MRDD) that 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.
MAGNETOM Free.Max may also be used for imaging during interventional procedures when performed with MR-compatible devices such as MR Safe biopsy needles.

MAGNETOM Free.Star:
MAGNETOM Free.Star system is indicated for use as a magnetic resonance diagnostic device (MRDD) that 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.

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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:

May 31, 2023

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
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Malvern, PA 19355, USA
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3. Device Name and Classification

Device/ Trade name:

MAGNETOM Free.Max
MAGNETOM Free.Star

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

4.1 Predicate Device

Trade name:	MAGNETOM Free.Max
510(k) Number:	K220575
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: MOS

Trade name:	MAGNETOM Free.Star
510(k) Number:	K220575
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	II
Product Code:	Primary: LNH Secondary: MOS

4.2 Reference Device

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

Trade name:	MAGNETOM Amira
510(k) Number:	K223343
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

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

5. Indications for Use

MAGNETOM Free.Max:

The indications for use for the subject device MAGNETOM Free.Max with syngo MR XA60A is extended to include MR imaging during interventional procedures compared to the predicate device MAGNETOM Free.Max with syngo MR XA50A:

MAGNETOM Free.Max system is indicated for use as a magnetic resonance diagnostic device (MRDD) that 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.

MAGNETOM Free.Max may also be used for imaging during interventional procedures when performed with MR-compatible devices such as MR Safe biopsy needles.

MAGNETOM Free.Star:

The indications for use for the subject device MAGNETOM Free.Star with syngo MR XA60A is the same as the predicate device MAGNETOM Free.Star with syngo MR XA50A:

MAGNETOM Free.Star system is indicated for use as a magnetic resonance diagnostic device (MRDD) that 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.

<u>Indications for use modification rationale for MAGNETOM Free.Max</u>:

The product features that support MR imaging during interventional procedures are released in subject device MAGNETOM Free.Max with syngo MR XA60A.

MR imaging during interventional procedures is already included in the reference device MAGNETOM Sola's indications for use and is 510(k) cleared (K221733, cleared on September 13, 2022).

This difference in indications for use does not alter the functionality in assisting diagnosis of the subject device as a magnetic resonance diagnostic device.

Therefore, this difference does not constitute a new intended use according to FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]".

6. Device Description

MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA60A include new and modified features compared to the predicate devices MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA50A (K220575, cleared on June 24, 2022).

Below is a high-level summary of the new and modified hardware and software features compared to the predicate devices MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA50A:

Hardware

New hardware features:

- Contour Knee coil
- Respiratory Sensor

Modified hardware features:

- myExam 3D Camera
- Host computer
- MaRS

Software

New Features and Applications:

- Injector coupling
- Respiratory Sensor Support
- myExam RT Assist (only for MAGNETOM Free.Max)
- myExam Autopilot Hip
- Deep Resolve Boost
- Complex Averaging
- HASTE_Interactive (only for MAGNETOM Free.Max)
- BEAT_Interactive (only for MAGNETOM Free.Max)
- Needle Intervention AddIn (only for MAGNETOM Free.Max)

Modified Features and Applications:

- Deep Resolve Sharp
- Deep Resolve Gain
- SMS Averaging

Other Modifications:

- Indications for Use (only for MAGNETOM Free.Max)
- MAGNETOM Free.Max RT Edition marketing bundle (only for MAGNETOM Free.Max)

Below Table 1 shows an executive summary of training and validation dataset of AI feature Deep Resolve Boost in subject devices:

Table 1. Training and validation dataset of AI feature

	Deep Resolve Boost
Sample size	26,473 2D slices
	Note: due to reasons of data privacy, we did not record how many individuals the datasets belong to. Gender, age and ethnicity distribution was also not recorded during data collection. Due to the network architecture, attributes like gender, age and ethnicity are not relevant to the training data.
Sample source	in-house measurements and collaboration partners
Dataset slipt	Training: 24,599 slices
	Validation: 1,874 slices
	Note: Data split maintained similar data distribution (e.g. contrast, orientation, field strength, …) in both training and validation datasets.
Equipments	1.5T and 3T MRI scanners [1]
Protocols	Representative protocols (T1, T2 and PD with and without fat saturation) which have been altered (e.g. to increase SNR, increase resolution or reduced acceleration).
Body regions	a broad range of different body regions
Clinical subgroups	No clinical subgroups have been defined for the datasets.
Counfouders	The input and output variables of the network have been derived from the same dataset so that no confounders exist for the training methodology.
Test statistics and test results	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR) and structural similarity index (SSIM). Additionally, images were inspected visually to ensure that potential artefacts are detected that are not well captured by the metrics listed above. After successful passing of the quality metrics tests, work-in-progress packages of the network were delivered and evaluated in clinical settings with cooperation partners.
Reference standard	The acquired datasets represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation and augmentation. This process includes further under-sampling of the data by discarding k-space lines, lowering of the SNR level by addition of noise and mirroring of k-space data.

[1] According to assessment, the network can be transferred to subject devices without the need of retraining with additional data sets.

7. Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA60A are substantially equivalent to the predicate devices listed in Table 2:

Table 2. Predicate devices and reference devices

Predicate Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Free.Max with *syngo* MR XA50A	K220575, cleared on June 24, 2022	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Free.Star with *syngo* MR XA50A	K220575, cleared on June 24, 2022	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
Reference Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Sola with *syngo* MR XA51A	K221733, cleared on September 13, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH
MAGNETOM Amira with *syngo* MR XA50M	K223343, cleared on March 23, 2023	LNH, LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Vida with *syngo* MR XA50A	K213693, cleared on Feburary 25, 2022	LNH, LNI, MOS	Siemens Healthcare GmbH

8. Technological Characteristics

The subject devices, MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA60A, 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 devices and predicate devices, including new and modified hardware and software features, and extended indications for use for MAGNETOM Free.Max. These 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 devices.
Please see below Table 3 and Table 4 for the comparison between subject devices and predicate/ reference devices.

Table 3. Hardware Comparison

Hardware	**Subject Devices**		**Predicate Devices**	
	MAGNETOM Free.Max with software *syngo* MR XA60A	**MAGNETOM Free.Star with software *syngo* MR XA60A**	**MAGNETOM Free.Max with** Error! Reference source not found. **(K220575)**	**MAGNETOM Free.Star with** Error! Reference source not found. **(K220575)**
Magnet System	Yes, same as predicate device		Yes	
RF System	Yes, same as predicate device		Yes	
Transmission technique – RF Body Coil	Yes, same as predicate device		Yes	
Gradient System	Yes, same as predicate device		Yes	

Patient Table	Yes, same as predicate device	Yes
Computer	Yes, modified compared to predicate device: -new host computer hardware -new MaRS hardware	Yes
Coils	Yes, new coil compared to predicate device: Contour Knee coil	Yes
Other HW components	Yes, Modified compared to predicate device: -myExam 3D Camera New compared to predicate device: -Respiratory Sensor	Yes

Table 4. Software Features Comparison

Software	**Subject Devices**		**Predicate Devices**	
	MAGNETOM Free.Max with software *syngo* MR XA60A	**MAGNETOM Free.Star with software *syngo* MR XA60A**	**MAGNETOM Free.Max with software *syngo* MR XA50A (K220575)**	**MAGNETOM Free.Star with *syngo* MR XA50A (K220575)**
Injector coupling	Yes, new feature migrated from reference device MAGNETOM Sola with syngo MR XA51A (K221733)		No	
Respiratory Sensor Support	Yes, new feature migrated from reference device MAGNETOM Amira with syngo MR XA50M (K223343)		No	
myExam RT Assist	Yes, new feature migrated from reference device MAGNETOM Sola with syngo MR XA51A (K221733)	No	No	
myExam AutoPilot Hip	Yes, new feature		No	
Deep Resolve Boost	Yes, new feature migrated from reference device MAGNETOM Vida with syngo MR XA50A (K213693)		No	
Complex Averaging	Yes, new feature		No	
HASTE_Interactive	Yes, new feature migrated from reference device MAGNETOM Sola with syngo MR XA51A (K221733)	No	No	
BEAT_Interactive	Yes, new feature migrated from reference device MAGNETOM Sola with syngo MR XA51A (K221733)	No	No	

Needle Intervention AddIn	Yes, new feature migrated from reference device MAGNETOM Sola with syngo MR XA51A (K221733)	No	No
Deep Resolve Sharp	Yes, modified compared to predicate device		Yes
Deep Resolve Gain	Yes, modified compared to predicate device		Yes
SMS Averaging	Yes, modified compared to predicate device		Yes

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	New and modified software features, pulse sequence types	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
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 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 XA60A 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
19-36	General	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	60601-1-2:2014 + AMD1:2020	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
5-129	General I (QS/ RM)	Medical devices - Part 1: Application of usability engineering to medical devices	62366-1: 2015 + AMD1:2020	ANSI AAMI IEC
13-79	Software/ Informatics	Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	IEC 62304:2006 + AMD1:2015	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
12-342	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	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)	10993-1:2018	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA60A have the same basic technological characteristics as the predicate device systems, MAGNETOM Free.Max and MAGNETOM Free.Star with *syngo* MR XA50A (Cleared with K220575 on June 24, 2022), with respect to the magnetic resonance features and functionalities. While there are some differences in technical features compared to the predicate devices, 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 devices and reference devices.

Siemens believes that MAGNETOM Free.Max and MAGNETOM Free.Star with software *syngo* MR XA60A are substantially equivalent to the currently marketed device MAGNETOM Free.Max and MAGNETOM Free.Star with syngo MR XA50A.