Siemens Medical Solutions USA, Inc.
Andrew Turner
Regulatory Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
Malvern, Pennsylvania 19355

July 1, 2021

Re: K210611
Trade/Device Name: MAGNETOM Free.Max
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: May 27, 2021
Received: June 1, 2021

Dear Andrew 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)*
K210611

Device Name
MAGNETOM Free.Max

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.

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Section 5 510(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: June 30, 2021

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

Andrew Turner,
Regulatory Affairs Technical Specialist
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3. Device Name and Classification

Device name:	MAGNETOM Free.Max
Trade name:	MAGNETOM Free.Max
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 Sempra
510(k) Number:	K183221
Clearance Date:	February 14, 2019
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 within that of the predicate device:

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, MAGNETOM Free.Max with software *syngo* MR XA40A, is an 80 cm bore Magnetic Resonance Imaging system with an actively shielded 0.55T superconducting magnet. Which is the first 0.55T MRI system for clinical use in the U.S.

MAGNETOM Free.Max is a MRI system that has equivalencies to the predicate device MAGNETOM Sempra with *syngo* MR XA12 (K183221, cleared on February 14, 2019). Whilst the subject device comes with significant new and modified hardware, the resultant customer clinical value is based on the predicate device MAGNETOM Sempra with *syngo* MR XA12 (K183221).

A high level summary of the new hardware comparing to the predicate device is provided below:

Hardware	New Hardware	– Magnet with no Quench Pipe including Autoramp up and Ramp down capability – Gradient Coil and Gradient Power Amplifier – System Cover – Patient Table (fixed with/without vertical drive) – RF system – Select&GO Display (TPAN_2G) and Control Panel (CPAN_2G) – Patient Communication Unit (Intercom with System Power On/Off Function integrated) – Computer system – myExam 3D Camera
	New Coils	– Body Coil – Head/Neck Coil – Spine Coil – BioMatrix Contour L Coil – Contour S Coil

In comparison to the predicate device, the subject device MAGNETOM Free.Max with software *syngo* MR XA40A brings new/modified software features:

Software	New Applications/ Software Features	– Sequence Booster – SMS Averaging – SWI with 3D segmented EPI – Ramp sampling mode – Skewed SPAIR – Accelerated Shim (STEAM-based field map) – Deep Resolve Gain – Deep Resolve Sharp

		The following new features for the subject device are migrated from the reference software version *syngo* MR XA30A (K202014, September 8, 2020): - Motion correction for Haste with multiple averages
	New Software Platform/ Workflow	- myExam Companion, which consists of: – myExam 3D camera – myExam Cockpit (new name for Dot Cockpit) – myExam Assist (new name for Dot Engines) – myExam Autopilot. - New Scanner User Interface: – Manual positioning – Select&GO extension – Guidance of general patient setup, and coil preparation - System functional safety test
Software	Modified Software Platform/ Workflow	- Improved System on/off/standby behavior

7. Substantial Equivalence

MAGNETOM Free.Max with software *syngo* MR XA40A is substantially equivalent to the predicate device:

Predicate Device	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Sempra with *syngo* MR XA12	K183221, cleared February 14, 2019	LNH LNI, MOS	Siemens Healthcare GmbH

The subject software *syngo* MR XA40A is modified based on the reference software XA30A; MAGNETOM C!, which is a low field device(0.35T) with permanent magnet is listed as a reference device as well:

Reference Devices	FDA Clearance Number and Date	Product Code	Manufacturer
MAGNETOM Aera with *syngo* MR XA30A	K202014, cleared September 8, 2020	LNH LNI, MOS	Siemens AG / Siemens Healthcare GmbH
MAGNETOM C!	K082331, cleared October 1, 2008	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.

8. Technological Characteristics

The subject device, MAGNETOM Free.Max with software *syngo* MR XA40A, 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.

There are some differences in technological characteristics between the subject device 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, pulse sequence types	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 and algorithms. - comparison images between the new / modified features and the predicate device features	
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

In order to practically learn Peripheral Nerve Stimulation (PNS) effects of the subject system, a clinical study of 12 individuals were conducted (see Results of stimulation study in Appendix 3).

No additional clinical tests were conducted to support substantial equivalence for the subject device; 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
SMS Averaging for TSE	[1] C. H. OH et al., 1984. Line-Integral Projection Reconstruction (LPR) with Slice Encoding Techniques: Multislice Regional Imaging in NMR Tomography, IEEE Trans Med Imaging. 1984; 3(4):170-178
Ramp sampling mode for Beat	[2] Matt A.Bernstein, Kevin F.king, Xiaohong Joe Zhou, Handbook Of MRI Pulse Sequences, 2004: P706-P712.
SWI with 3D segmented EPI	[3] Zwanenburg JJ, et al. Fast high resolution whole brain T2* weighted imaging using echo planar imaging at 7T. Neuroimage. 2011; 56:1902-1907. [4] Liu W, et al. 3D Flow Compensated Interleaved EPI for a Fast High-Resolution Susceptibility-Weighted Imaging at 1.5T. Proc. Intl. Soc. Mag. Reason. Med 2019; 27: 3326.
Accelerated Shim (STEAM-based field map)	[5] Nehrke, K., and Börnert, P. "DREAM—a novel approach for robust, ultrafast, multislice B1 mapping." *Magnetic resonance in medicine* 68.5 (2012): 1517-1526.
Skewed SPAIR	[6] Hwang, T. L., van Zijl, P. C., and Garwood, M. 1999. Asymmetric adiabatic pulses for NH selection. *J. Magn. Reson.* 138: 173–177. [7] Pfeuffer J. et al. “Zoomed Functional Imaging in the Human Brain at 7 Tesla with Simultaneous High Spatial and High Temporal Resolution” NeuroImage 17(1), 2002, p. 272-286.
Deep Resolve Gain	[8] Kellman P. et al. Image Reconstruction in SNR Units: A General Method for SNR Measurement. MRM 2005; 54:1439. Erratum in MRM 2007; 58:311.
	[9] Blu T. et al. The SURE-LET approach to image denoising. IEEE Transactions on Image Processing 16(11):2778-86
Deep Resolve Sharp	[10] Yulun Zhang, et al. Residual Dense Network for Image Super-Resolution, IEEE conference on computer vision and pattern recognition. 2018
	[11] Eirikur Agustsson, Radu Timofte. NTIRE 2017 Challenge on Single Image Super-Resolution: Dataset and Study. CVPRW, 2017. 5
	[12] Justin Johnson, et al. Perceptual Losses for Real-Time Style Transfer and Super-Resolution. European conference on computer vision. Springer, Cham, 2016

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 device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

MAGNETOM Free.Max with software *syngo* MR XA40A 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, 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
5-40	General	Medical devices - Application of risk management to medical devices	14971, Ed. 2:2007	ISO
5-114	General	Medical devices – Application of usability engineering to medical devices	62366, Edition 1.0:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304:2006 + A1:2015	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
2-258	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 with software *syngo* MR XA40A has the same basic technological characteristics as the predicate device, MAGNETOM Sempra with *syngo* MR XA12, with respect to the magnetic resonance features and functionalities. And the indications for use of the subject device falls within the intended use of the predicate device.

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 Free.Max with software *syngo* MR XA40A is substantially equivalent to the currently marketed device MAGNETOM Sempra with software *syngo* MR XA12 (K183221, cleared on February 14, 2019).