March 28, 2023

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

Re: K223343
Trade/Device Name: MAGNETOM Amira; MAGNETOM Sempra
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS, LNI
Dated: March 3, 2023
Received: March 3, 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 (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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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)*

K223343

Device Name

MAGNETOM Amira;
MAGNETOM Sempra

Indications for Use *(Describe)*

The 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.
The 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.

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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:
October 31, 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
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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 Amira
MAGNETOM Sempra
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

4.1 Predicate Device

Trade name:	MAGNETOM Amira
510(k) Number:	K183221
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 Sempra
510(k) Number:	K183221
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

4.2 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 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

5. Intended Use

The indications for use for the subject devices are the same as that of the predicate device:

The 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.

The 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 Amira and MAGNETOM Sempra with *syngo* MR XA50M include new and modified features comparing to the predicate devices MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR XA12M (K183221, cleared on February 14, 2019).

Below is a high-level summary of the new and modified hardware and software features comparing to the predicate devices MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR XA12M:

Hardware

Dedicated coils only for MAGNETOM Sempra with *syngo* MR XA50M:

- Flex Large 8 Coil
- Flex Small 8 Coil
- Flex 8 Coil Interface

Software

New Features and Applications:

- SMS TSE DIXON
- SE EPI MRE (EP2D_SE_MRE)
- ZOOMit PRO
- High bandwidth inversion recovery
- WAVE-CAIPI SWI (GRE_WAVE)
- Deep Resolve Sharp
- Deep Resolve Gain
- Deep Resolve Boost
- Table positioning mode
- Coil independent pulse sequences
- BLADE Diffusion
- TSE MoCo
- MR protocols module (new name for “MR Protocol Manager“)
- Automatic fiducial detection
- Access-i
- myExam Brain Autopilot
- SMS Averaging

Modified Features and Applications:

- 3D ASL (TGSE_ASL)
- myExam LiverLab Assist

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

Table 1. Training and validation dataset of AI features

	Deep Resolve Boost	**Deep Resolve Sharp**
Sample size	26,473 2D slices	13,977 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	in-house measurements
Dataset slipt	Training: 24,599 slices	Training: 11,920 slices
	Validation: 1,874 slices	Validation: 2,057 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	
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. In a total of seven peer-reviewed publications 427 patients were successfully scanned on 1.5T and 3T. The investigations covered following body regions: prostate, abdomen,	The impact of the network has been characterized by several quality metrics such as peak signal-to-noise ratio (PSNR), structural similarity index (SSIM), and perceptual loss. In addition, the feature has been verified and validated by inhouse tests. These tests include visual rating and an evaluation of image sharpness by intensity profile comparisons of reconstruction with and without Deep Resolve Sharp. Both tests show increased edge sharpness.

	liver, knee, hip, ankle, shoulder, hand and lumbar spine. All publications have concluded that the work-in-progress package and the reconstruction algorithm can be beneficially used for clinical routine imaging. No cases have been reported where the network led to a misinterpretation of the images or where anatomical information has been altered, suppressed, or introduced. In most cases the new algorithm has been used to acquire images faster and significant time savings are reported.	
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.	The acquired datasets represent the ground truth for the training and validation. Input data was retrospectively created from the ground truth by data manipulation. k-space data has been cropped such that only the center part of the data was used as input. With this method corresponding low-resolution data as input and high-resolution data as output / ground truth were created for training and validation.

7. Substantial Equivalence

MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA50M are substantially equivalent to the predicate devices list in Table 2:

Table 2. Predicate devices and reference devices.

Predicate Device	**FDA Clearance Number and Date**	**Product Code**	**Manufacturer**
MAGNETOM Amira with *syngo* MR XA12M	K183221, cleared on February 14, 2019	LNH, LNI, MOS	Siemens Shenzhen Magnetic Resonance Ltd.
MAGNETOM Sempra with *syngo* MR XA12M	K183221, cleared on February 14, 2019	LNH, LNI, 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 Free.Max with *syngo* MR XA50A	K220575, cleared on June 24, 2022	LNH, MOS	Siemens Shenzhen Magnetic Resonance Ltd.

8. Technological Characteristics

The subject devices, MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA50M, 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. Please see below Table 3 and Table 4 for the comparison between subject devices and predicate/ reference devices.

Table 3. Hardware Comparison

Feature	**Subject Device**	**Predicate Device**	**Subject Device**	**Predicate Device**
	MAGNETOM Amira with software syngo MR XA50M	**MAGNETOM Amira with software syngo MR XA12M (K183221)**	**MAGNETOM Sempra with software syngo MR XA50M**	**MAGNETOM Sempra with software syngo MR XA12M (K183221)**
Magnet System	same		same	
RF System	same		same	
Transmission Technique	same		same	
Gradient System	same		same	
Patient Table	same		same	
Computer	same		same	
Coils	same		New coils: -Flex Large 8, -Flex Small 8, -Flex 8 Coil Interface	-
Other HW components	same		same	

Comparison results: new local coils are introduced to MAGNETOM Sempra with *syngo* MR XA50M comparing to the predicate device. These differences have been tested and non-clinical data concluded no impact on safety and effectiveness of the device.

Table 4. Software Features Comparison

Feature	Subject Device	Subject Device	Reference Device	Predicate Device	Predicate Device
	MAGNETOM Amira with *syngo* MR XA50M	**MAGNETOM Sempra with *syngo* MR XA50M**	**MAGNETOM Sola with *syngo* MR XA51A (K221733)**	**MAGNETOM Amira with *syngo* MR XA12M (K183221)**	**MAGNETOM Sempra with *syngo* MR XA12M (K183221)**
SMS for TSE DIXON	same			No	
SE EPI MRE	same			No	
ZOOMit PRO	same			No	
High bandwidth inversion recovery	same			No	
WAVE-CAIPI SWI	same			No	
Deep Resolve Sharp	same			No	
Deep Resolve Gain	same			No	
Deep Resolve Boost	same			No	
Table positioning mode	same			No	
Coil independent pulse sequences	same			No	
BLADE Diffusion	same			No	
TSE MoCo	same			No	
MR Protocols Module	same			No	
Automatic fiducial detection	same			No	
Access-i	same			No	
myExam Brain Autopilot	same			No	
SMS Averaging [1]	same		No	No	
3D ASL	same, modified comparing to predicate device			Yes	
myExam LiverLab Assist	same, modified comparing to predicate device			Yes	

[1] SMS Averaging for TSE was cleared in reference device MAGNETOM Free.Max with *syngo* MR XA50A (K220575). SMS Averaging is made available for both TSE and TSE DIXON pulse sequence in subject devices.

Comparison results: new and modified software features are introduced to subject devices comparing to the predicate devices. These differences have been tested and non-clinical data concluded no impact on safety and effectiveness of the devices.

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 local coils, new and modified software features, pulse sequence types	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices
Software verification and validation	mainly new and modified software features	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

The following performance testing for local coils was conducted on the predicate devices and can be reused for the subject devices:

Performance Test	Tested Hardware or Software	Source/Rationale for test
Performance bench test	- SNR and image uniformity measurements for coils - Heating measurements for coils	Guidance for Submission of Premarket Notifications for Magnetic Resonance Diagnostic 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 Amira and MAGNETOM Sempra with software *syngo* MR XA50M 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. 3.2:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971:2019	ISO
5-96	General	Medical devices – Application of usability engineering to medical devices	62366 Edition 1.0 2015	AAMI ANSI IEC
13-32	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	AAMI ANSI IEC
12-195	Radiology	NEMA MS 6-2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	MS 6-2008 (R2014)	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA
2-156	Biocompatibility	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1:2018/(R) 2013	AAMI ANSI ISO

12. Conclusion as to Substantial Equivalence

MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA50M have the same intended use and same basic technological characteristics as the predicate devices system, MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR XA12M (K183221, cleared on February 14, 2019), 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 device and reference device.

Siemens believes that MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA50M are substantially equivalent to the currently marketed devices MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR XA12M.