Siemens Medical Solutions USA, Inc.
% Mr. Martin Rajchel
Regulatory Affairs Specialist
40 Liberty Blvd., Mail Code 65-1A
MALVERN PA 19355

February 14, 2019

Re: K183221
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, LNI, MOS
Dated: November 19, 2018
Received: November 20, 2018

Dear Mr. Rajchel:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183221

Device Name

MAGNETOM Amira, MAGNETOM Sempra

Indications for Use *(Describe)*

Your MAGNETOM MR 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 MR 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

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

Date Prepared November 19, 2018

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR § 807.92.

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

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

Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Establishment Registration Number: 3002808157

2. Contact Information

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3. Device Name and Classification

Trade Names	MAGNETOM Amira MAGNETOM Sempra
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	Class II
Product Code:	Primary: LNH Secondary: LNI, MOS

4. Legally Marketed Predicate Devices

Trade Names	MAGNETOM Amira MAGNETOM Sempra MAGNETOM Sola
510(k) Numbers	K173600, Cleared on December 19, 2017 K163211, Cleared on January 27, 2017 K181322, Cleared on October 5, 2018
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR § 892.1000
Classification:	Class II
Product Code:	Primary: LNH Secondary: LNI, MOS

5. Device Description

Software *syngo* MR XA12M is the latest software version for MAGNETOM Amira and MAGNETOM Sempra. It supports the existing “A Tim+Dot system” configuration for MAGNETOM Amira and MAGNETOM Sempra, and the newly introducted “A BioMatrix system” configuration for MAGNETOM Amira.

Software Updates

Software version *syngo* MR XA12M for MAGNETOM Amira and MAGNETOM Sempra includes software applications migrated from the secondary predicate device MAGNETOM Sola with *syngo* MR XA11A (K181322). Only minor adaptations were needed to support the system specific hardware and optimize the sequences/protocols. In addition, new software features, Segmented TOF, HASTE with variable flip angle, SMS in RESOLVE and QDWI, are also introduced in *syngo* XA12M.

Compared to the previously cleared software version *syngo* MR E11S, the following software applications are made available for the subject devices:

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System

Completely new features:

The following new features for *syngo* MR XA12M are not previously cleared:

- Segmented ToF (feature to reduce scan time compared to conventional ToF acquisition)
- HASTE with variable flip angle (technique for improving the acquisition efficiency in Turbo Spin-Echo (TSE) via lengthening turbo factors)

Migrated features from the secondary predicate device, MAGNETOM Sola with *syngo* MR XA11A (K181322):

Software features

- **Features from *syngo* MR XA11A (K181322) now made available unchanged for the subject devices**:
  - SliceAdjust (framework for pulse sequence types that allow dynamic adjustments to measured sub-volumes)
  - Compressed Sensing GRASP-VIBE (conduct dynamic contrast-enhanced abdominal exams in free breathing)
  - Compressed Sensing Cardiac Cine (free breathing Cardiac Cine scaning which is integrated into the BEAT pulse sequence type)
  - RetroGating (Compressed Sensing Cardiac Cine acquisitions which splits data acquisition over multiple heartbeats configured to perform complete sampling of the cardiac cycle without prior definition of an acquisition window)
  - SPACE with CAIPIRINHA (3D SPACE pulse sequence type with iPAT mode CAIPIRINHA)
  - Cardiac Dot Flow Add-In (extension of Cardiac Dot Engine to support blood flow measurements)
  - PCASL mode (extension of ASL pulse sequence types with a new blood labeling mode)
  - BEAT_IRTTT (extension of BEAT_IRT sequence with a multi-slice functionality and additional parameters)
  - Noise masking (feature to remove the noise floor in outer regions)
  - Turbo Suite (marketing bundle of components for accelerated MR imaging offered for the subject devices)

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System

- **Features available for the previously cleared *syngo* MR E11S (K173600 / K163211), modified and cleared with *syngo* MR XA11A (K181322), and included unchanged in the subject devices**:
  - Dixon fat/water separation (improvement for a more robust assignment of local fat and water regions to the respective image)
  - Pre-Scan-Normalize (improvement to correct MRI images for local coil sensitivity variations and to generate homogenous MRI images)
  - iPAT / TSE Reference Scan (Improvements in VIBE and HASTE pulse sequence types to improve the image quality)
  - MRCP in SPACE (improvement of the image quality for MR Cholangiopancreatography (MRCP) acquisitions based on the SPACE pulse sequence type)
  - MR Elastography
    - Replacement of existing masking by a masking performed on the pre-scan images used within the pre-scan normalize (PSN) functionality
    - Optimization of pulse sequence type timing
    - Changes in MEG time period (no longer fixed to the wavelength of the MEG and implementation of a reduced MEG period)

Software / Platform

Modifications to the general software / platform that have been cleared with the secondary predicate device with *syngo* MR XA11A (K181322) and included unchanged in the subject devices with *syngo* MR XA12M:

- Patient Registration and Scheduler consolidated
- Spectroscopy Add-in (enables planning on non-distortion corrected images for spectroscopy)
- MR View&GO (Addition of Mosaic View (view mode to scroll through dimensions instead of space) and 4D Movie Toolbar (movie toolbar to navigate the 4th dimension))
- Prior Handling (for the display of available priors)
- System shutdown unattended by the user
- Dot Cockpit (additional features for handling scan pulse sequences and offline Dot Cockpit)
- Teamplay Protocols Interface (interface to support external pulse sequence management systems)

Other Modifications and / or Minor Changes

Other modifications that have been cleared with the secondary predicate device with *syngo* MR XA11A (K181322) and are included unchanged in the subject devices with *syngo* MR XA12M:

- SAR Assistant (two additional options for selection)
- Improved Adjustments (frequency adjustment optimized for more reliable water peak detection, and FastView adjustments extended to all data selectable in the user interface)
- Unilateral Hip (added in Large Joint Dot Engine - user workflow optimized)

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System
- GRE RefScan (external GRE RefScan extended to multiple pulse sequence types) - Asymmetric saturation pulses (support for regional saturation with an asymmetric shape added for BOLD imaging) - CP Mode modification ("RF Transmit Mode" provided as part of patient registration based on the IEC 60601-2-33 standard)		
The following are only applicable for **MAGNETOM Amira** (both configurations). **Completely new feature:** - SMS in RESOLVE and QDWI (SMS imaging utilized to either speed up 2D acquisitions with multiple slices or to increase the number of acquired slices without increasing the measurement time with the RESOLVE / QDWI sequence) **Migrated Features from *syngo* MR XA11A (K181322) included unchanged in the subject device:** - GOKnee3D (examination which comprises the AutoAlign knee localizer and two SPACE with CAIPIRINHA sequences to support fast high-resolution 3D exams of the knee) - Whole-Body Dot Engine (supports multi-region examinations with consistent settings for spatial resolution, image contrast, and breath-hold capacity) - SMS in TSE (Simultaneous Multi Slice (SMS) support for TSE)		n/a

Hardware Updates

The hardware updates to the subject devices are listed below:

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System
New/Modified Hardware		
Hardware updates which are the same as that of the secondary predicate device MAGNETOM Sola with *syngo* MR XA11A (K181322): - *syngo* Acquisition Workplace and monitor - System Start Timer (implemented in Electronics and Power Cabinet (EPC)) **Modified from the previously cleared *syngo* MR E11S (K173600/ K163211) for MAGNETOM**		

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System
Amira and MAGNETOM Sempra: - Magnet - Patient Table - Body Coil - MaRS - Intercom		
Local Coils (See details below)		
iTX Extremity 18 Flare (Completely new coil)	iTX Extremity 18 Flare (Completely new coil)	n/a
n/a	BM Body 13 (A 1.5T BioMatrix Coil) (Completely new coil)	n/a
Shoulder Shape 16 (Cleared with K181322)	Shoulder Shape 16 (Cleared with K181322)	n/a
UltraFlex Large 18 (Cleared with K181322)	UltraFlex Large 18 (Cleared with K181322)	UltraFlex Large 18 (Cleared with K181322)
UltraFlex Small 18 (Cleared with K181322)	UltraFlex Small 18 (Cleared with K181322)	UltraFlex Small 18 (cleared with K181322)
n/a Note: Body 13 coil has been cleared with MAGNETOM Amira (K152283)		Body 13 (cleared with K152283)
Others (See details below)		
n/a	Modified from the previously cleared *syngo* MR E11S (K173600/ K163211) - New system Cover with Touch UI and Control - New Siemens Branding: "Siemens Healthineers" logo - Respiratory Sensor (new respiratory sensor loops integrated into the BM Body 13 coil for measuring the change of electro-magnetic signal resulting from the shifting of the tissue and organs). To support the respiratory sensor, the following components are modified: - RFIS (Radio Frequency	n/a

1. MAGNETOM Amira		2. MAGNETOM Sempra
A Tim+Dot System	A BioMatrix System (New configuration)	A Tim+Dot System
	Infrastructure System) - RCCS (Receive Coil Channel Selector)	

6. Indication for Use

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

> Your MAGNETOM MR 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 MR 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.

7. Substantial Equivalence

MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR XA12M are substantially equivalent to the following predicate devices:

Subject device: MAGNETOM Amira with *syngo* MR XA12M

Primary Predicate Device	**FDA Clearance Number**	**FDA Clearance Date**	**Product code**
MAGNETOM Amira with *syngo* MR E11S	K173600	December 19, 2017	LNH LNI,MOS
Secondary Predicate Device	**FDA Clearance Number**	**FDA Clearance Date**	**Product code**
MAGNETOM Sola with software *syngo* MR XA11A	K181322	October 5, 2018	LNH LNI,MOS
Reference Device	**FDA Clearance Number**	**FDA Clearance Date**	**Product code**
syngo.via VB30A based on *syngo*.via VB10A	K150843	April 24, 2015	LLZ

Subject device: MAGNETOM Sempra with *syngo* MR XA12M

Primary Predicate Device	**FDA Clearance Number and Date**	**FDA Clearance Date**	**Product code**

MAGNETOM Sempra with *syngo* MR E11S	K163211	January 27, 2017	LNH LNI,MOS
Secondary Predicate Device	**FDA Clearance Number and Date**	**FDA Clearance Date**	**Product code**
MAGNETOM Sola with software *syngo* MR XA11A	K181322	October 5, 2018	LNH LNI,MOS
Reference Device	**FDA Clearance Number**	**FDA Clearance Date**	**Product code**
syngo.via VB30A based on *syngo*.via VB10A	K150843	April 24, 2015	LLZ

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device

The subject devices, MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA12M, are substantially equivalent to the predicate devices with regard to the operational environment, programming language, operating system, and performance.

MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA12M conforms to the standard for medical device software (IEC 62304:2006) and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics (see Section 5 – Device Description above) between the subject devices and predicate devices, including

- completely new software applications (Segmented TOF, HASTE with variable flip angle, SMS in RESOLVE and QDWI)
- two completely new coils and hardware modified from the previously cleared *syngo* MR E11S (K173600/ K163211)

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 devices.

9. Nonclinical Performance Testing

The following performance testing was conducted on the subject devices

- Sample clinical images were taken for the new coils, new and modified software features, and pulse sequence types.
- Image quality assessments of all new/modified pulse sequence types and algorithms were completed. In some cases a comparison of the image quality was made between the new/modified features and the predicate features.
- Software verification and validation testing was completed in accordance with the FDA guidance document, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,*" dated May 11, 2005.

- Performance testing was completed in accordance with the FDA guidance document, "*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices,*" dated November 18, 2016.

The results from each set of tests demonstrate that the subject devices perform as intended and are thus substantially equivalent to the predicate devices to which they have been compared.

MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA12M conform to the applicable 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	14971:2007/(R) 2010 (Corrected 4 October 2007).	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)	

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	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)	10993-1:2009/(R) 2013	AAMI ANSI ISO

No clinical tests were conducted to support the claim of substantial equivalence between the subject and predicate device. Sample clinical images have been provided in accordance with the FDA guidance document, “Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices,” dated November 18, 2016.

10. General Safety and Effectiveness Concerns

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 ISO 14971:2007 compliance to identify and provide mitigation of potential hazards in a risk analysis early in the design phase and continuously throughout the development of the product. These risks are controlled via measures realized in hardware and software development, testing, and product labeling. To minimize risks, Siemens adheres to recognized and established industry practices and standards, such as the IEC 60601-1 series, to minimize electrical and mechanical risks. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

11. Conclusion as to Substantial Equivalence

The subject devices, MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA12M, have the same intended use and different technological characteristics compared to the predicate devices with respect to the magnetic resonance features and functionalities. While the new and modified software and hardware features provide additional capabilities compared to the primary predicate devices, MAGNETOM Amira and MAGNETOM Sempra with *syngo* MR E11S (K173600; K163211), most of the them have been migrated from the secondary predicate device, MAGNETOM Sola with software *syngo* MR XA11A (cleared with K181322).The new

features that were not migrated from *syngo* MR XA11A do not raise new questions of safety and effectiveness. All features have been verified and/or validated to support the claim of substantial equivalence to the predicate devices.

Siemens believes that MAGNETOM Amira and MAGNETOM Sempra with software *syngo* MR XA12M are substantially equivalent to the predicate devices MAGNETOM Amira (K173600), MAGNETOM Sempra (K163211), and MAGNETOM Sola (K181322).