Siemens Medical Solutions USA, Inc.
Martin Rajchel
Regulatory Affairs Specialist
40 Liberty Boulevard, Mail Code 65-1A
Malvern, Pennsylvania 19355

December 19, 2017

Re: K173600
Trade/Device Name: MAGNETOM Amira
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: November 20, 2017
Received: November 21, 2017

Dear Martin 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Robert Ochs

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)*
K173600

Device Name
MAGNETOM Amira

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.

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
MAGNETOM Amira with software *syngo* MR E11S

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

Date Prepared November 20, 2017

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
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 Name	MAGNETOM Amira with software *syngo* MR E11S
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 Device

Trade Name	MAGNETOM Amira with Software syngo MR E11N
510(k) Number	K152283, Cleared December 24, 2015
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

The subject device, MAGNETOM Amira with *syngo* MR E11S, is a modification of the previously cleared predicate device, MAGNETOM Amira with *syngo* MR E11N (K152283). Software version *syngo* E11S for MAGNETOM Amira includes software applications migrated from the previously cleared MAGNETOM Aera systems with *syngo* MR E11C and E11C – AP02 (K153343 and K163312). Only minor adaptations were needed to support the system specific hardware and optimize the sequence/protocols. The following are the software applications migrated from previously cleared software to the subject device:

- fast TSE
  - Improvements in BLADE Imaging
- SMS EPI
  - Simultaneous Multi Slice Imaging
- Quiet DWI
  - Noise reduced sequence for diffusion weighted imaging
- GOBrain
  - Supports brain examination in short acquisition time
- GOBrain+
  - GOBrain adaptation to support protocols developed for contrast enhanced imaging of the brain

Listed below are the hardware updates to the MAGNETOM Amira with *syngo* MR E11S:

- Updated MRAWP/MRWP (Syngo Acquisition Workplace/ Syngo Workplace) based on the new host platform—HP Z440.
- Endorectal interface and adapter to connect the Endorectal Coil (to be ordered separately) to the MAGNETOM Amira systems.

The MAGNETOM Amira with software version *syngo* MR E11S will be offered ex-factory (new production) as well as in-field upgrades for the currently installed MAGNETOM Amira systems.

6. Indication for Use

The indications for use for the subject device is the same as the predicate device and is as follows:

> 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

The MAGNETOM Amira with *syngo* MR E11S is substantially equivalent to the following device:

Predicate Device	FDA Clearance Number	FDA Clearance Date	Product Code
MAGNETOM Amira with software version *syngo* MR E11N	K152283	December 24, 2015	LNH, LNI, MOS

As described above, the MAGNETOM Amira with *syngo* MR E11S includes features already cleared on the following devices:

Reference Device	FDA Clearance Number	FDA Clearance Date	Product Code
Software *syngo* MR E11C for the MAGNETOM System Aera	K153343	April 15, 2016	LNH, LNI, MOS
MAGNETOM Aera and MAGNETOM Skyra with syngo MR E11C - AP02 Software	K163312	January 27, 2017	LNH, LNI, MOS

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

The subject device MAGNETOM Amira with *syngo* E11S is substantially equivalent to the predicate device, MAGNETOM Amira with *syngo* MR E11N, with regard to the operational environment, programming language, operating system, and performance.

The subject device, MAGNETOM Amira with *syngo* MR E11S, conforms to the IEC 62304, Edition 1.1, 2015-06, standard for software medical devices and other relevant IEC and NEMA standards.

While there are some differences in technological characteristics between the subject device and predicate device including new and modified software applications and hardware additions, these differences have been tested and the conclusions from the non-clinical data suggests that the features bear an equivalent safety and performance profile as that of the predicate device.

9. Nonclinical Performance Testing

The following performance testing was conducted on the subject device:

- Sample clinical images were taken for the endorectal coil.
- 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 device performs as intended and is thus substantially equivalent to the predicate device to which it has been compared.

MAGNETOM Amira with *syngo* E11S conforms to the following FDA recognized and international IEC and ISO standards:

Recogniton 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,	AAMI ANSI
19-1	General II (ES/EMC)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	60601-1-2 Edition 3: 2007-03	IEC
12-271	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. 3.1:2013	IEC
5-40	General I (QS/RM)	Medical devices - Application of risk management to medical devices	14971 Second Edition 2007-03-01	ISO
5-89	General I (QS/RM)	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	60601-1-6 Edition 3.1 2013-10	IEC
13-32	Software/Informatics	Medical device software - Software life cycle processes	IEC 62304 Edition 1.1 2015-06	AAMI ANSI IEC

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 provide for safe and effective use of the device.

Risk management is ensured via compliance with ISO 14971:2007 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 risk. 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

There are no changes to the indications for use for the subject device as compared to that of the legally marketed predicate device, MAGNETOM Amira with software version *syngo* MR E11N (K152283).

While the new and modified software and hardware features provide additional capabilities compared to the predicate device, the additional capabilities are currently cleared features of the reference device MAGNETOM Aera with software *syngo* MR E11C and E11C – AP02 (K153343; K163312) and do not raise new questions of safety and effectiveness. All features have been verified and validated to support the claim of substantial equivalence to the predicate device.

Siemens believes that the subject device, MAGNETOM Amira with *syngo* MR E11S, is substantially equivalent to the predicate device, MAGNETOM Amira with *syngo* MR E11N.