



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.  
% Cordell Fields, Esq.  
Regulatory Affairs Specialist  
51 Valley Stream Parkway  
MALVERN PA 19355

December 24, 2015

Re: K152283  
Trade/Device Name: MAGNETOM Amira  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: LNH, LNI, MOS  
Dated: November 23, 2015  
Received: November 24, 2015

Dear Mr. Fields:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 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 <b>Indications for Use</b>	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)

K152283

Device Name

MAGNETOM Amira

Indications for Use (Describe)

MAGNETOM Amira 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.

MAGNETOM Amira 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.

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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 Safe Medical Device Act 1990 and 21 CFR § 807.92.

### I. General Information

<b>Establishment</b>	Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Mail Code D02 Malvern, PA 19355, USA
<b>Registration Number</b>	2240869
<b>Date Prepared</b>	August 10, 2015
<b>Manufacturer</b>	Siemens Shenzhen Magnetic Resonance Ltd. Siemens MRI Center, Gaoxin C. Ave., 2 <sup>nd</sup> Hi-Tech Industrial Park 518057 Shenzhen China <b>Registration Number:</b> 3004754211
<b>Contact Person</b>	Mr. Cordell L. Fields, Esq. Regulatory Affairs Technical Specialist Siemens Healthcare Siemens Medical Solutions USA, Inc. 40 Liberty Blvd Mail Code 65-1A Malvern, PA 19355, USA Phone: (610) 219-8518 Fax: (610) 448-1787
<b>Device Name</b>	MAGNETOM Amira with Software <i>syngo</i> MR E11N
<b>Trade Names:</b>	MAGNETOM Amira
<b>Classification Name:</b>	Magnetic Resonance Diagnostic Device (MRDD)
<b>Classification Panel:</b>	Radiology
<b>CFR Code:</b>	21 CFR § 892.1000
<b>Classification:</b>	Class II
<b>Product Code:</b>	Primary: LNH, Secondary: LNI, MOS

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## **II. Safety and Effectiveness Information Supporting Substantial Equivalence**

### **Indications for Use**

The MAGNETOM Amira 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 Amira may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-Safe biopsy needles.

### **Device Description**

MAGNETOM Amira (1.5T) is an MRI system that is substantially equivalent to the previously cleared primary predicate device MAGNETOM Aera (K141977, cleared November 19, 2014) and secondary predicate device MAGNETOM ESSENZA (K130262, cleared March 1, 2013).

The MAGNETOM Amira utilizes a superconducting magnet design. The open bore, whole body scanners are designed for increased patient comfort. They focus on ergonomics and usability to simplify the MR workflow.

The MAGNETOM Amira systems will be available in a fixed configuration.

### **Technological Characteristics**

While the MAGNETOM Amira with Software syngo MR E11N, the subject device, has the same basic technological characteristics as the predicate devices, there are some differences which do not affect safety or effectiveness. These differences are summarized below and are also addressed in further detail in this submission (Section 12.4).

The MAGNETOM Amira system has some different technological characteristics in comparison to the predicate devices which include:

- Different bore diameter and length of the magnet
  - Different current output and power supply of the gradient system
  - Differences in the RF system concerning the maximum number of RF channels and the maximum number of receiving coil elements
  - Patient table maximum vertical and horizontal range difference
  - New coils to be used with the subject device
    - Head/Neck 10
    - Spine 18
    - Body 13
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- Peripheral Angio 16
- Breast 4
- Extremity 12
- iTX Extremity 18
- Shoulder Small/Large 6
- Wrist 8
- Foot/Ankle 10
- 10 minute exam application/feature

The subject and the primary predicate device, MAGNETOM Aera (K141977, cleared November 19, 2014) are substantially equivalent with regard to the following:

- MR image acquisition steps/features
- Operational environment, programming language, operating system and performance
- Conformance to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

### **Nonclinical Tests**

The following performance testing was conducted on the subject device:

- The coils were tested for SNR, image uniformity, and heating.
- All other software features were verified and validated.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

### **Clinical Tests**

No clinical tests were conducted to support the subject device and the substantial equivalence argument; however, clinical images were provided to support the new coils for the subject device.

### **Safety and Effectiveness**

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 a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards in a risk analysis beginning early in the design phase and continuing throughout the development of the product. These risks are controlled via measures realized in software development, SW 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 operators are healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

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The MAGNETOM Amira with software *syngo* MR E11N conforms to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

**Substantial Equivalence**

The MAGNETOM Amira with software *syngo* MR E11N is substantially equivalent to the following devices:

<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>	<i>Product Code</i>
Siemens MAGNETOM Aera (1.5T) (Primary Predicate)	K141977	Nov 19th 2014	LNH, LNI, MOS
Siemens MAGNETOM ESSENZA (1.5T) (Secondary Predicate)	K130262	Mar 1st 2013	LNH

**Reference Device:**

<i>Reference Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>	<i>Product Code</i>
MAGNETOM Spectra	K121160	July 16 <sup>th</sup> 2012	LNH, LNI, MOS

**Conclusion as to Substantial Equivalence**

MAGNETOM Amira with Software *syngo* MR E11N has the same intended use and the same basic technical characteristics as the predicate devices:

MAGNETOM Aera (K141977, cleared November 19, 2014) and MAGNETOM ESSENZA (K130262, cleared March 1, 2013), with respect to the magnetic resonance features and functionalities.

MAGNETOM Amira with Software *syngo* MR E11N will be used for acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra). The predicate devices, MAGNETOM Aera (K141977) and MAGNETOM ESSENZA (K130262), are also capable of acquiring MR images (transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra). Though there are differences between the subject device and the predicate devices, which include the new and modified software and hardware features, the conclusions from the nonclinical data suggest that the features (of different technological characteristics with respect to the predicate devices) bear an equivalent safety and performance profile as that of the predicate and reference device.

MAGNETOM Amira with Software *syngo* MR E11N has similar functionality as the predicate devices, and does not introduce new issues of safety or effectiveness. Therefore, Siemens is of the opinion that MAGNETOM Amira with Software *syngo* MR E11N does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed devices, MAGNETOM Aera (K141977) and MAGNETOM ESSENZA (K130262).