February 15, 2019

Siemens Medical Solutions USA, Inc.
% Cordell L. Fields, Esq.
Regulatory Affairs Specialist
40 Liberty Boulevard, Mailcode 65-1A
MALVERN PA 19355

Re: K190138
Trade/Device Name: MAGNETOM Aera
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, LNI, MOS
Dated: January 28, 2019
Received: January 29, 2019

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. 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)*

K190138

Device Name

MAGNETOM Aera

Indications for Use *(Describe)*

Your 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.
Your MAGNETOM system 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.

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

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

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355

Date Prepared: January 28, 2019

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, Mail Code 65-1A
Malvern, PA 19355, USA
Establishment Registration Number: 2240869

Manufacturing Sites:
Siemens Healthcare GmbH
Henkestrasse 127
91052 Erlangen, Germany
Establishment Registration Number: 3002808157

SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
Siemens MRI Center
Hi-Tech Industrial park (middle)
Gaoxin C. Ave., 2nd
Shenzhen 518057, P.R. CHINA
Establishment Registration Number: 3004754211

2. Contact Person:

Cordell L. Fields, Esq.
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355, USA
Phone: (610) 448-6469
Fax: (610) 640-4481
E-mail: Cordell.Fields@siemens-healthineers.com

3. Device Name and Classification:

Device Name	MAGNETOM Aera - Mobile Solution with Tim Dockable Table
Trade Name	MAGNETOM Aera
Classification Name	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS

4. Legally Marketed Predicate Device:

Device Name	MAGNETOM Aera with *syngo* MR E11C - AP01 software
Trade Names:	MAGNETOM Aera
510(k) Number:	K182299, cleared October 26, 2018
Classification Name	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1000
Device Class:	II
Primary Product Code:	LNH
Secondary Product Code:	LNI, MOS

5. Intended Use

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

Your 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.

Your MAGNETOM system 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.

6. Device Description:

The mobile configuration for MAGNETOM scanners enables customers to relocate the MRI System to different locations and therefore provide imaging services to hospitals or locations where fixed installations are not possible or feasible.

For MAGNETOM Aera a mobile configuration is already available on the market with a fixed patient table. Within this premarket notification the Tim Dockable Table is being made available for the MAGNETOM Aera - Mobile Solution to enable customers to use the mobile MR Tim Dockable Table as an extension to their MRI fleet.

In order to support the addition of the Tim Dockable Table a hardware modification is necessary. A support bracket will be modified to secure the Tim Dockable Table during repositioning of the Trailer. For this modification specifications for the trailer manufacturers, which need to undergo certification, are adapted.

The MAGNETOM Aera - Mobile Solution with Tim Dockable Table described within this submission does not contain any software modifications.

Workflow	Release of Tim Dockable Table to the MAGNETOM Aera - Mobile Solution to enable customers to use the mobile MR table as an extension to their MRI fleet
Hardware	Modification of an existing support bracket to secure the Tim Dockable Table during repositioning of the Trailer
Software	The MAGNETOM Aera - Mobile Solution with Tim Dockable Table described within this submission does not contain any software modification compared to the predicate device.

7. Technological Characteristics

The subject device, MAGNETOM Aera - Mobile Solution with Tim Dockable Table, has the same technological characteristics as the predicate device, MAGNETOM Aera with *syngo* MR E11C-AP01, (K182299, cleared October 26, 2018) with regard to the operational environment, programming language, operating system, and performance.

The hardware was modified to introduce a support bracket to secure the Tim Dockable Table during repositioning of the Trailer. Furthermore the Requirements to the Trailer Manufacturer need to consider the dockable table.

The MAGNETOM Aera - Mobile Solution with Tim Dockable Table conforms to the standard for software medical devices (IEC 62304:2015) and other relevant IEC and NEMA standards.

While there is a hardware difference between the subject device and predicate device, in this case only hardware modification of a bracket which impacts the overall workflow, the MAGNETOM Aera system itself is not changed. This

hardware modification which impacts the overall workflow has been tested for safety and effectiveness; it is safe and effective.

8. Nonclinical Tests

The following performance testing was conducted on the subject device:

- General Performance Testing
- Acoustic Noise Testing
- Environmental Testing (Weather Influences)

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.

9. Clinical Tests

No clinical tests were conducted to support substantial equivalence for the subject device.

10. 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 ISO 14971:2007 compliance 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 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. Software development is carried out according to the IEC 62304 standard for medical device software. Furthermore, the device is intended for healthcare professionals familiar with and responsible for the acquisition and post processing of magnetic resonance images.

The MAGNETOM Aera - Mobile Solution with Tim Dockable Table conforms to the applicable FDA recognized and international IEC, ISO and NEMA.

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
19-4	General	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

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
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 diagnostic	60601-2-33 Ed. 3.2 B:2015	IEC
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-89	General	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
5-96	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
13-79	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	IEC
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 - 3.20 (2016)	NEMA

11. Substantial Equivalence and Conclusion

The subject device, MAGNETOM Aera - Mobile Solution with Tim Dockable Table, has the same intended use, indications for use, and technological characteristics as the predicate device, MAGNETOM Aera with *syngo* MR E11C-AP01, (K182299).

The hardware was modified to introduce a support bracket to secure the Tim Dockable Table during repositioning of the Trailer.

While there is a hardware difference between the subject device and predicate device, in this case only hardware modification of a bracket which impacts the overall workflow, the MAGNETOM Aera system itself is not changed. This hardware modification which impacts the overall workflow has been tested for safety and effectiveness; it is safe and effective.

Siemens believes that the subject device, MAGNETOM Aera - Mobile Solution with Tim Dockable Table is substantially equivalent to the predicate device, MAGNETOM Aera with *syngo* MR E11C-AP01.