Siemens Medical Solutions USA, Inc.
Cordell Fields
Regulatory Affairs Specialist
65 Valley Stream Parkway, Mail Code 65-1A
Malvern, Pennsylvania 19355

November 14, 2017

Re: K172531
Trade/Device Name: Biograph mMR with mMR Angio Transfer Option
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: OUO, LNH, LNI, KPS
Dated: August 21, 2017
Received: August 22, 2017

Dear Cordell 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.

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,

Michael D. O'Hara For

Robert A. 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)*

K172531

Device Name
Biograph mMR with mMR Angio Transfer Option

Indications for Use *(Describe)*

The Siemens MR-PET system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders.

The MR is intended to produce transverse, sagittal, coronal and oblique crosssectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles.

The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer.

The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Section 5 510(k) Summary

Biograph mMR with mMR Angio Transfer Option

Company Name and Address	Siemens Medical Solutions USA. Inc. 40 Liberty Boulevard Mail Code 65-1A Malvern, PA 19355, USA **Registration Number**: 2240869
Date Prepared	August 21, 2017
Conformance statement:	This 510(k) summary of 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.

1. General Information

Importer / Distributor	Siemens Medical Solutions USA. Inc. 40 Liberty Boulevard Mail Code 65-1A Malvern, PA 19355, USA **Registration Number**: 2240869
Location of Manufacturing Site	Siemens Healthcare GmbH Henkestrasse 127 Erlangen Bayern, Germany 91052 **Registration Number**: 3002808157

2. Contact Persons

Contact Person

Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
65 Valley Stream Parkway
Mail Code 65-1A
Malvern, PA 19355, USA
Phone: (610) 448-6469
Cell: (610) 306-3167
Fax: (610) 640-4481
E-mail: cordell.fields@siemens-healthineers.com

Alternate Contact Person

Kimberly Rendon
Sr. Manager Regulatory Affairs
Siemens Medical Solutions USA, Inc.
65 Valley Stream Parkway
Mail Code 65-1A
Malvern, PA 19355, USA
Phone: (610) 448-6480
Fax: (610) 448-1787
E-mail: Kimberly.rendon@siemens-healthineers.com

3. Device Name and Classification

Trade Name: Classification Name	Biograph mMR with mMR Angio Transfer Option Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel:	Radiology
Classification Regulation	21 CFR § 892.1200 21 CFR § 892.1000
Device Class:	II
Primary Product Code:	OUO
Secondary Product Codes:	LNH, LNI, KPS

4. Legally Marketed Predicate Devices

Trade Name	Biograph mMR with Software *syngo* MR E11P
510(k) #	K163234 cleared February 28, 2017
Classification Name	Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel:	Radiology
Classification Regulation	21 CFR § 892.1200 21 CFR § 892.1000
Device Class:	II
Primary Product Code:	OUO
Secondary Product Codes:	LNH, LNI, KPS
Recall Information	"There are no Recalls for this Predicate Device."

5. Device Description

The new mMR Angio Transfer Option is being introduced for the Biograph mMR system.

The new option is intended to provide a patient transfer from the SIEMENS Artis Q and Artis Q.zen (K123529) or Artis zee/zeego SW VC21 (K141574) System to the Biograph mMR and vice versa.

To achieve this functionality a Transferboard Artis (further named as Transferboard) will be used where the patient is located and transferred. This Transferboard can be adapted on the standard table of the Artis Q and Artis Q.zen (K123529) or Artis zee/zeego SW VC21 (K141574) System. The standard table is identical for all models. By swiveling the Artis Q, Artis Q.zen or Artis zee /zeego table (standard function) the Transferboard will be positioned in front of the Biograph mMR. Via the Guiding Slide Way the Transferboard is pushed manually on the Table Top of the Biograph mMR.

The Guiding Slide Way is also included in the option and is installed on the Table Top of the Biograph mMR instead of a regular patient cushion.

The Transferboard is also used to move the patient into the bore of the Biograph mMR for further diagnostic imaging.

The basic device and its functionality remain unchanged except for the following modifications:

- Coil Adapter Cover (CAC): The Coil Adapter Cover will replace the standard mMR coil adapter cover on the foot end of the mMR tabletop to enable the overtraveling of the Transferboard (TFB).
- Guiding Slide Way (GSW): A Guiding Slide Way (GSW) will be adapted on the existing Biograph mMR tabletop. This is a foldable option and can be removed for diagnostic mMR examination in case the transfer option is not needed.
- Transferboard (TFB): The Transferboard (TFB) is intended to transfer the patient. The patient remains on this board during the whole intraoperative procedure.
- Patient Cushion (LGH): The Patient Cushion is laid on the Transferboard (TFB) for comfortable reclining.
- Fixation Belts: The Fixation Belts are used for preventing the patient to fall of the Transferboard and Patient Cushion during transport, surgery and imaging.
- Transfer Support Cart (TSC): The Transfer Support Cart is part of the option. It ensures that both tables have the same height and that there are no vibrations during transfer due to load changes on the patient tables

The new mMR Angio Transfer Option for the Biograph mMR system requires the most recent Device Software, syngo MR E11P software cleared via 510(k) on February 28, 2017 (K163234).

Advantage

The new features on the Biograph mMR with mMR Angio Transfer Option enables the handover of a patient previously examined by SIEMENS Artis Q, Artis Q.zen or Artis zee/zeego System and vice versa. The advantage is that the patient can simply stay on the Transfer Board. There is no need to lift him or her from one patient support system to another.

6. Indication for Use

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

The Siemens MR-PET system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders.

The MR is intended to produce transverse, sagittal, coronal and oblique crosssectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles.

The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer.

The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.

7. Substantial Equivalence

The subject device, mMR Angio Transfer Option for the Biograph mMR, was developed from the previous version of the Biograph mMR (with software version *syngo* MR E11P).

As described above, only the hardware for the device was modified. Software is not affected.

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

Technological Characteristics

The new mMR Angio Transfer Option for the Biograph mMR has the same technological characteristics as the predicate device Biograph, mMR with *syngo* MR E11P (K163234, cleared February 28, 2017).

The subject device is substantially equivalent to the predicate device. As described above, the main changes are mechanical and enable the transfer of the patient form the Artis Q, Artis Q.zen or Artis zee/zeego System to the Biograph mMR.

9. Nonclinical Performance Testing

The following performance testing was conducted on the subject device for covering the mMR Angio Transfer Option for the Biograph mMR. Existing performance test for the Biograph mMR remain valid.

- Mechanical Test according to IEC 60601-1 / ANSI AAMI ES 60601-1
- System verification and validation.

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.

mMR Angio Transfer Option for the Biograph mMR 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, “Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices”, issued in 2016.
For the mMR Angio Transfer Option for the Biograph mMR, new testing for the standards indicated by an asterisk (*) was conducted for the proposed modifications. Standards not indicated by an asterisk are also tested for the Biograph mMR however their validity is not affected by the proposed modifications, i.e. the old evidence is still valid.

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
19-1	General	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	Medical devices – Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
* 5-67	General	Medical devices – Application of usability engineering to medical devices	62366:2007	IEC
13-32	Software	Medical device software – Software life cycle processes	62304:2006	AAMI ANSI IEC
12-232	Radiology	Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	MS 4-2010	NEMA

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
12-288	Radiology	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)	MS 9-2008	NEMA
12-300	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set 03/16/2012 Radiology	PS 3.1 – 3.20 (2016)	NEMA
12-265	Radiology	Performance measurements of positron emission tomographs	NU 2-2012	NEMA
* 2-220	Biocompatibility	Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process	10993-1 Fourth Edition 2009-10-15	ISO

Table 1: Recognized Consensus Standards for mMR Angio Transfer Option

10. General Safety and Effectiveness Concerns

Instructions for use are included in the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design.

Also, the Biograph mMR with mMR Angio Transfer Option is continually monitored, and if an error occurs, the system functions will be blocked, and an error message will be displayed.

Risk management according to ISO 14971:2007 is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing. Furthermore, the operators are health care professionals familiar with and responsible for the mMR examinations to be performed.

11. Conclusion as to Substantial Equivalence

mMR Angio Transfer Option for the Biograph mMR has the same intended use and the same technological characteristics as the predicate device Biograph mMR with *syngo* MR E11P (K163234).

The new features on the Biograph mMR with mMR Angio Transfer Option enables the handover of a patient previous examined by SIEMENS Artis Q, Artis Q.zen or Artis zee/zeego System and vice versa. The advantage is that the patient can simply stay on the Transfer Board. There is no need to lift the patient from one patient support system to another.

These modifications improve the user's workflow to enable an intraoperative procedure together with SIEMENS Artis Q and Artis Q.zen (K123529) or Artis zee/zeego SW VC21 (K141574) System.
The differences between the subject device and the predicate device include incorporation / adaptations of cleared features from the MAGNETOM Artis Combi Suite (K140253) which do not raise new issues of safety or effectiveness.

Therefore, Siemens believes that the subject device, Biograph mMR System with mMR Angio Transfer Option is substantially equivalent to the predicate device, Biograph mMR with *syngo* MR E11P.