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

May 11, 2020

Re: K200213
Trade/Device Name: Biograph mMR with syngo MR E11P-AP01 system software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: OUO, LNH, LNI, KPS
Dated: April 10, 2020
Received: April 16, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.,
Director,
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

K200213

Device Name

Biograph mMR with *syngo* MR E11P-AP01 system software

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 sys tem 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. De- pending on the region of interest, approved contrast agents may be used, as described in their label ing. 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 pre- cisely 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.

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510(k) Summary: Biograph mMR with syngo MR E11P-AP01

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

Date Prepared: January 22, 2020

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.

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

2. Contact Person:

Mr. Cordell L. Fields, Esq.
Regulatory Affairs Technical Specialist
Siemens Medical Solutions USA, Inc.
Phone: (610) 448-6469
E-mail: cordell.fields@siemens-healthineers.com

3. Device Name and Classification:

Common / Usual Name	mMR Biograph
Trade Name	Biograph mMR with *syngo* MR E11P-AP01 system software
Classification Name	Emission Computed Tomography System
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1200
Device Class:	II

Primary Product Code: OUO
Secondary Product Code: LNH, LNI, KPS

4. Intended Use

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.

5. Device Description:

The subject device, syngo MR E11P-AP01 system software for the Biograph mMR system, is a modification of the previously cleared predicate device Biograph mMR with syngo MR E11P system software (K163234, cleared February 28, 2017). The subject device has been modified to include the new mMR 32 Head coil for combined MR-PET usage as well as improvements to the system software syngo MR E11P.

- Improvement of the SPACE pulse sequence type with:

- CAIPIRINHA acquisition technique named as CAIPIRINHA SPACE (migrated from previously cleared reference device K173592)
- Additional magnetization preparation mode “Non-sel. T2 prep. IR” for brain imaging with improved dark-fluid contrast.

– Implementation of “CP-only” RF transmission mode based on the requirements of 60601-2-33 Ed. 3.2:2015.

6. Summary of Technological Characteristics

While there are differences in technological characteristics between the subject device Biograph mMR with software syngo MR E11P-AP01 and the predicate device Biograph mMR with syngo MR E11P (K163234, cleared February 28, 2017), these differences have been tested and the conclusions from the non-clinical data suggests that the feature bear an equivalent safety and performance profile as that of the predicate device.

The new mMR 32Ch Head Coil for combined MR-PET usage is essentially based on the 32Ch Head Coil, initially cleared with K072909 (November 05, 2007), most recently cleared with MAGNETOM Verio with syngo MR E11D (K181613). The improvement of SPACE pulse sequence type is transferred unchanged from MAGNETOM Skyra with Software syngo MR E11C-AP04, cleared with K173592.

Syngo MR E11P-AP01 SW conforms to the standard for software medical devices (IEC 62304:2006) and IEC as well as NEMA standards.

7. Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images were taken with the modified sequences and the migrated mMR 32Ch Head Coil.
- Image quality assessments of the modified sequences and the mMR 23Head coil were completed.
- Quantitative image evaluations of the mMR 32 Head Coil for MR and PET images were completed.
- Validation of the newly generated attenuation map by phantom testing
- 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”

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.

8. Clinical Tests

Clinical images are provided to support the migrated coil as well as the improved software features of the subject device.

9. 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.

The Biograph mMR with syngo MR E11P-AP01 conforms 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

Recognition Number	Product Area	Title of Standard	Reference Number and date	Standards Development Organization
5-40	General	Medical devices - Application of risk management to medical devices	14971 Second edition 2007-03-01	ISO
5-114	General	Medical devices – Application of usability engineering to medical devices	62366-1:2015	AAMI ANSI IEC
13-32	Software	Medical device software - Software life cycle processes	62304 Edition 1.1 2015-06	IEC
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
2-220	Biocom-patibility	Biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)	10993-1:2009/(R) 2013	AAMI ANSI ISO
12-288	Radiology	Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI)	MS 9-2008	NEMA
12-265	Radiology	Performance measurements of positron emission tomographs	NU 2-2012	NEMA

10. Substantial Equivalence

The subject device, Biograph mMR with syngo MR E11P-AP01, was developed from the previous software version VE11P.

Predicate Device	FDA Clearance Number	Product Code	Manufacturer
Biograph mMR with Software syngo MR E11P	K163234, cleared February 28, 2017	OUO, LNH, LNI, KPS	Siemens AG / Siemens Healthcare GmbH

11. Conclusion as to Substantial Equivalence

syngo MR E11P-AP01 software for the Biograph mMR has the same intended use and different technological characteristics as the predicate device Biograph mMR with syngo MR E11P (K163234).

While there are differences in technological characteristics between the subject device and predicate device, these differences have been tested and the

conclusions from the non-clinical data suggests that the feature bear an equivalent safety and performance profile as that of the predicate device.

The new features on the Biograph mMR with syngo MR E11P-AP01 provides improved capabilities and options to the user; and reduces image artifacts.

The differences between the subject device and the predicate device, include incorporation / adaptation of the mMR 32 Head coil and improvements on the SPACE pulse sequence type as well as the implementation of “CP-only” RF transmission mode based on the requirements of 60601-2-33 Ed. 3.2:2015.

Therefore, Siemens believes that the subject device, Biograph mMR System with software syngo MR E11P-AP01 does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed device Biograph mMR with syngo MR E11P.