DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 28, 2017

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

Re: K163234
Trade/Device Name: Biograph mMR with *syngo* MR E11P system software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO and LNH, LNI, KPS
Dated: January 27, 2017
Received: January 30, 2017

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k163234

Device Name
Biograph mMR with syngo MR E11P 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 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.

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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 Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment Siemens Medical Solutions USA. Inc.
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Registration Number: 2240869

Date Prepared November 15, 2016

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Device Name:	*syngo* MR E11P software for Biograph mMR
Trade name:	Biograph mMR with *syngo* MR E11P system software
Classification Name:	Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Classification Panel:	Radiology
Regulation Number:	21 CFR § 892.1200 21 CFR § 892.1000
Device Class:	II
Primary Product Code:	OUO

Secondary Product Codes: LNH, LNI, KPS

II. Safety and Effectiveness Information Supporting Substantial Equivalence

Intended 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.

Device Description

The subject device, *syngo* MR E11P system software, is being introduced for the Biograph mMR system.

The *syngo* MR E11P SW includes new sequences, new features and minor modifications of already existing features. A high level summary of the new sequences and features is included below.

Migrated sequences and features from the previously cleared secondary predicate devices MAGNETOM Verio with *syngo* MR D13A and Siemens E-line Software with MAGNETOM Skyra with *syngo* MR E11C (K153343) are not described separately as these are commercially available and no changes are introduced for this system.

Improvement in Attenuation Correction

Atlas-based bones in µ-map generation

The bone attenuation map is computed based on a regular 4-compartment (air, lung, fat, water) segmentation from a Dixon sequence. As improvement, the bone information is added to these µ-maps with a model-based bone segmentation algorithm using continuous linear attenuation coefficients (LACs) for bone to represent the variation in cortical bone density in different anatomical areas.

The model consists of the most relevant bones in the body torso in terms of overall attenuation. It consists of the skull, spine, pelvis and femur bone as individual components.

MR based FoV extension for attenuation correction – (HUGE)

In this SW version *syngo* MR E11P the attenuation map can be improved by using an optional MR-based FoV extension technique. This technique requires an additional MR measurement optimized for distortion reduced acquisition of the patient's arms resting along the body at the edge of the FoV.

New and Modified Features

Multimodal (Elastic) Motion Correction (BodyCOMPASS)

Elastic motion correction is introduced to reduce the effect of blur induced by respiratory motion during a PET acquisition. As a basic principle, periodic motion information is collected by means of the MR as a 4D image series and used for PET to

- bin the PET counts into separate respiratory states
- provide a mapping for each spatial position and each respiratory state to a reference state, which can be used in the PET reconstruction

Hence, the resulting PET image combines the advantages of a gated PET image with reduced motion blur while preserving the signal-to-noise ratio of static non-gated reconstruction.

Improvement in DIXON fat water separation

In this SW version *syngo* MR E11P the DIXON reconstruction technique (fat/water separation) is improved. The improved algorithm is based on global optimization and thus minimizes the probability of local fat/water swaps where part of water image is wrongly assigned to fat image and/or vice versa.

Dot Cockpit (DotGO), including PET Workflow

The previously cleared DotGO with the Dot Cockpit and the MR only Dot Engines is now available on the Biograph mMR with *syngo* MR E11P. The configuration of PET workflows is now integrated into the Dot Cockpit for higher productivity.

This modification increases the robustness and usability for the clinical workflow with the new PET Planning Group, PET Planning Step and special reduced MR Parameter cards while still offering the full parameter access with detail views, PET and AC specific steps with their parameter cards.

Improved MR PET Workflow

With the software *syngo* MR E11P a set of protocols are included in order to run a clinical whole body workflow with 5 beds, AC, T1-, T2-, DWI-contrast, adjustments and SAR pauses in 45 minutes.

In this workflow the AC protocol is acquired in high resolution (1.3 mm * 1.3mm in plane) using CAIPIRINHA acceleration. Alternatively, an AC protocol in conventional resolution (2.6 mm * 2.6 mm in plane) using CAIPIRINHA acceleration is available in order to reduce the acquisition time for AC measurement in case T1-contrast is not requested from AC scan.

Other Software Improvements

NEMA NU 2:2012

As it is possible that routine NEMA testing may be required to retain ACR accreditation, Siemens has developed an optional software package which enables a Biograph mMR system user to quantify image quality for certain performances according to the most recent available NEMA standards.

Improvements in Retro Recon Task Card

In the RetroRecon Task Card of the Biograph mMR with *syngo* MR E11P, an additional identifier in the list of the parameter Attenuation Correction indicates gated µ-Maps.

Furthermore a Tooltip for the Attenuation Correction parameter explains the identifier.

For respiratory gating a new Respiratory Curve Display shows the recorded cushion signal as well as the specified gates for some gating types.

Third Party Interface for AC

An Interface functionality is added to the *syngo* MR E11P software to import attenuation maps of third party components for hardware attenuation correction.

Other Modifications

Front Cover Panel Refresh for Biograph mMR

The Biograph mMR with *syngo* MR E11P will receive new system covers. The graphic design of the cover has been changed to give the systems an updated and more modern look to highlight the introduction of a new software version.

MaRS - technology for Biograph mMR

The modified control system of the Biograph mMR integrates the functions of the AMC (Advanced Measurement Control) and MRIR (MR Image Reconstructor) into one computer called MaRS (Measurement and Reconstruction System).

The MaRS system performs sequence control and image reconstruction without additional MRIR. The introduction of the MaRS was part of the secondary predicate device MAGNETOM Verio with *syngo* MR D13A (K121434). This is now updated to new computer hardware with this submission.

Physiological Monitoring Unit (PMU)

The Physiological Measurement Unit (PMU) was modified to improve the accuracy of triggers on the respiration signal. The PMU provides ECG, respiration and peripheral pulse as well as external trigger input to control of the MR imaging sequences for synchronization.

Syngo MR Software Features

Other features were included unchanged from the secondary predicate devices (K121434 and K153343). These features expand the Biograph mMR's MR scanning capabilities and update the feature set to be more similar to currently released Siemens MR software.

Technological Characteristics

Software *syngo* MR E11P for Biograph mMR has the same technological characteristics as the primary predicate device Biograph mMR with *syngo* MR B20P (K133226, cleared November 12, 2013).

The subject device is substantially equivalent to the predicate devices with regard to the operational environment, programming language, operating system and performance.

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

While *syngo* MR E11P SW offers new and modified SW features, the modified SW features with respect to the primary and secondary predicate devices have the same technological characteristics as the predicate device systems. Further, this submission

includes minor hardware modifications and a cosmetic modification to the front cover panel. These do not represent a change in technological characteristics.

Nonclinical Tests

The following performance testing was conducted on the subject device

- Sample clinical images were taken for particular new and modified sequences.
- Acoustic noise measurements were performed for quiet sequences
- Image quality assessments of all new/modified sequences and algorithms, were completed.
- 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.

Clinical Tests

The following studies were conducted to support the substantial equivalence argument:

- Comparison study of an extended MR FoV and truncation correction (HUGE) with truncated data without FoV extension and additionally to an established approach of PET-based FoV extension.
- Quantitative comparison study of attenuation maps of CT-based AC and MR-based AC method for whole-body PET/MR imaging combining Dixon-based soft-tissue segmentation and model-based bone estimation.
- Quantitative comparison study of SUV estimation for MR-based AC methods to a reference CT AC comparing:
  - standard Dixon 4-compartment segmentation alone,
  - Dixon with a superimposed model-based bone compartment, and
  - Dixon with a superimposed bone compartment and linear attenuation correction optimized specifically for brain tissue.

Additionally clinical images were provided to support the substantial equivalence for the new software features of 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.

The *syngo* MR E11P software 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, 1998.

Substantial Equivalence

The subject device, Biograph mMR with *syngo* MR E11P, was developed from the previous software version VB20P. However, additional software features that were not part of this previous software version will now be migrated into *syngo* MR E11P. Therefore secondary predicate devices are listed below that support various sequences, software and workflow features as noted above.

Predicate Device Information

Primary Predicate Device	FDA Clearance Number	Product Code	Manufacturer
Biograph mMR with Software *syngo* MR B20P	K133226, cleared November 12, 2013	OUO, LNH, LNI, KPS	Siemens AG / Siemens Healthcare GmbH
Secondary Predicate Device	**FDA Clearance Number**	**Product Code**	**Manufacturer**
Software *syngo* MR D13A for the MAGNETOM Verio	K121434 cleared November 5, 2012	LNH, LNI, MOS	Siemens AG / Siemens Healthcare GmbH
Software *syngo* MR E11C for the MAGNETOM Skyra	K153343, cleared April 15, 2016	LNH, LNI, MOS	Siemens AG / Siemens Healthcare GmbH

Conclusion as to Substantial Equivalence

syngo MR E11P software for the Biograph mMR has the same intended use and the same technological characteristics as the primary predicate device Biograph mMR with *syngo* MR B20P (K133226).

The Biograph mMR is evolving with respect to the MANGETOM Verio with *syngo* MR D13A (K121434) and Siemens E line Software with MAGNETOM Skyra with *syngo* MR E11C (K153343). The new features on the Biograph mMR with *syngo* MR E11P make the system and software more user-friendly. These modifications improve the user's workflow and reduce the complexity of certain imaging procedures; providing additional output, information, and options to the user; and reduce image artifacts.

The differences between the subject device and the predicate devices, include incorporation / adaptation of cleared features from the MAGNETOM Skyra with *syngo* MR E11C (K153343), the MAGNETOM Verio with *syngo* MR D13 (K121434), and extensions of *syngo* MR B20P features (K133226), which give the Biograph mMR system better capabilities with respect to the predicate devices, but have the same technological characteristics as the predicate devices, and do not introduce any new issues of safety or effectiveness.

Therefore, Siemens believes that the subject device, Biograph mMR System with software *syngo* MR E11P is substantially equivalent to the predicate devices, Biograph mMR with *syngo* MR B20P, the MAGNETOM Verio with *syngo* MR D13A and MAGNETOM Skyra with *syngo* MR E11C.