This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

5.1 General Information

Establishment

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Registration Number 2240869

NOV 12 2013

Manufacturer

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SIEMENS SHENZHEN MAGNETIC RESONANCE LTD.
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Contact Person

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Device Name Software *syngo* MR B20P for Biograph mMR

CFR Code 21 CFR § 892.1200

Classification Class II

Product Codes OUO
Classification Name Magnetic Resonance Diagnostic Device (MRDD), Emission Computed Tomography System, MR Coils

5.2 Information Supporting Substantial Equivalence

DEVICE DESCRIPTION

The Biograph mMR systems are combined Magnetic Resonance Imaging and Positron Emission Tomography scanners. The Biograph mMR systems provide registration and fusion of high-resolution metabolic, physiologic and anatomic information from the two major components of each system (PET and MR) acquired simultaneously and isocentrically.

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.

Software *syngo* MR B20P is a new software version for the Siemens Biograph mMR systems that were previously cleared under K103429 (running software version *syngo* MR B18P).

New scanners will be manufactured with *syngo* MR B20P; existing scanners can be upgraded to this software version. The new software version includes new software features, coil modifications and other modified hardware for the Biograph mMR systems.

Summary of New Features with Biograph mMR Software *syngo* MR B20P:

Software

- New applications/software/sequences
  - Reconstruction improvements
  - Usability improvements
  - Quality control improvements
  - New sequences (e.g. for joints and liver imaging)
  - Multi-Nuclear Spectroscopy

Hardware

- Modified coils:
  - 4 Channel Special Purpose Coil
  - mMR Head/Neck Coil
  - mMR Breast Coil

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 cross-sectional 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.

NONCLINICAL TESTS

The following performance testing was conducted on the subject device:

- The coils were tested for SNR, image uniformity, heating, and hybrid mode.
- The performance parameters of MNO Spectroscopy were phantom-tested.
- All software features were verified and validated.
- PET performance testing in accordance with NEMA NU:2

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

There were not any clinical tests conducted to support the subject device and the substantial equivalence argument, however clinical images are provided to better support the descriptions in Section 11 of the modified features of the subject device.

SUBSTANTIAL EQUIVALENCE

Biograph mMR System with software *syngo* MR B20P is substantially equivalent to the following predicate devices:

Primary Predicate Device	FDA Clearance Number	FDA Clearance Date	Main Product Code
Biograph mMR with software *syngo* MR B18P	K103429	June 8, 2011	OUO

Supporting Devices for Components	FDA Clearance Number	FDA Clearance Date	Main Product Code
syngo MR B19 for MAGNETOM Verio	K123938	February 12, 2013	LNH
Biograph mCT with software PET*syngo* VG50	K123737	January 29, 2013	90 KPS and 90 JAK

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 beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

The Biograph mMR System with software *syngo* MR B20P conform 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 CONCLUSION

There are no changes to the Indications for Use for the subject device, compared to that of the predicate Biograph mMR system with and the Biograph mMR System with software *syngo* MR B20P.

While the new hardware and software provides the user with additional capabilities compared to the subject system with the previous software version *syngo* MR B18P, it has the same technological characteristics as that of the predicate devices. The Biograph mMR is evolving with respect to the Biograph mCT with software PET*syngo* VG50 (K123737) and the MAGNETOM Verio with *syngo* MR B19 (K123938). The new features on the Biograph mMR with *syngo* MR B20P make the systems 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 Biograph mCT with software PET*syngo* VG50 (K123737), the MAGNETOM Verio with *syngo* MR B19 (K123938), and extensions of *syngo* MR B18P features (K103429), which give the Biograph mMR system similar 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 B20P is substantially equivalent to the predicate devices, Biograph mMR with *syngo* MR B18 and the MAGNETOM Verio with *syngo* MR B19.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

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NADIA SOOKDEO
REGULATORY AFFAIRS TECHNICAL SPECIALIST
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MALVERN PA 19355

Re: K133226
Trade/Device Name: Biograph mMR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Dated: October 18, 2013
Received: October 21, 2013

Dear Ms. Sookdeo:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

JANINE MORRIS
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) k133226

Device Name: **Software *syngo* MR B20P for Biograph mMR**

Indications for 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.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health