DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 14, 2017

GE Medical Systems, LLC
% Ms. Janice Sich
Regulatory Affairs Manager
3200 N. Grandview Blvd.
Waukesha WI 53188

Re: K163619
Trade/Device Name: SIGNA PET/MR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: OUO
Dated: December 21, 2016
Received: December 22, 2016

Dear Ms. Sich:

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)* k163619

Device Name
SIGNA PET/MR

Indications for Use *(Describe)*

The SIGNA PET/MR 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 ofthe 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.

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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In accordance with 21 CFR 807.92 the following summary of information is provided:	
Date:	December 21, 2016
Primary Contact Person:	Janice M Sich Regulatory Affairs Manager, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6312 Fax: 414-908-9585
Secondary Contact Person:	Glen Sabin Regulatory Affairs Director, MR GE Healthcare, (GE Medical Systems, LLC) Phone: 262-521-6848 Fax: 414-908-9585
Device Trade Name:	SIGNA PET/MR
Common/Usual Name:	Magnetic Resonance Diagnostic Device / Positron Emission Tomography (PET) System
Classification Names:	Emission Computed Tomography System per 21 CFR 892.1200
Product Code:	OUO
Predicate Device:	SIGNA PET/MR (K142098)
Device Description:	The GE SIGNA PET/MR system is a combined Magnetic Resonance Diagnostic Device (MRDD) and Positron Emission Tomography (PET) scanner. The system is designed for whole body oncology, neurology and cardiology examinations. The SIGNA PET/MR system provides simultaneous acquisition of high-resolution metabolic and anatomic information from the two major components of each system (MR and PET). Additional components of the system include: a patient table and both the acquisition and processing workstations with associated software. The SIGNA PET/MR includes a 3.0T superconducting magnet, gradient coil and body coil. The system includes dual drive capabilities. The SIGNA PET detectors are integrated into the MR bore. This allows for simultaneous, precisely aligned whole body MR and PET acquisition. The PET subsystem supports Time of Flight (ToF). The SIGNA PET/MR software is used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

Indications for Use:	The SIGNA PET/MR 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. 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. 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.
Comparison of Intended Use	The proposed modifications do not impact the indications for use of the device, therefore the intended use has not changed compared to the predicate. The modifications outlined within this submission have the same intended use as the predicate device in accordance with the FDA's guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]", dated 28 July 2014.
Technology:	The SIGNA PET/MR with the proposed software modifications employs the same fundamental scientific technology as the predicate device. This subject of this premarket notification includes modifications to MR Attenuation Correction compared to the predicate device.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The features that are the subject of this premarket notification are software only features that comply with the following voluntary

	standards: • AAMI/ANSI 62304 • AAMI/ANSI ES60601-1 • IEC 60601-2-33 The following quality assurance measures were applied to the development of subject features: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Safety testing (Verification) • Simulated use testing (Validation) Non-clinical tests have been summarized in the verification and validation testing. The testing was completed with passing results per the pass/fail criteria defined in the test cases. This supports substantial equivalence to its predicate because the software features were developed under quality assurance Design Controls. <u>Summary of Clinical Tests:</u> Sample clinical images, qualitative and quantitative comparisons compared to the predicate MR Attenuation Correction technology are included in this submission to support substantial equivalence of the modified features.
<u>Conclusion:</u>	GE Healthcare considers the SIGNA PET/MR with the modified software to be as safe, as effective, and performance is substantially equivalent to the predicate device.