GE Medical Systems, LLC
% Mr. Brian Zielski
Regulatory Affairs Leader
3200 N. Grandview Blvd.
WAUKESHA WI 53188

January 20, 2022

Re: K213709
Trade/Device Name: SIGNA PET/MR
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: OUO
Dated: November 22, 2021
Received: November 24, 2021

Dear Mr. Zielski:

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

Julie Sullivan
Associate 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213709

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 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.

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

K213709

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 22, 2021
Submitter:	GE Medical Systems, LLC 3200 N. Grandview Blvd. Waukesha, WI 53188
Primary Contact:	Brian R. Zielski Regulatory Affairs Leader Phone: 262-227-3596 Email: brian.zielski@ge.com
Secondary Contact:	Andrew Menden Senior Regulatory Affairs Manager Phone: 262-308-5719 Email: andrew.menden@ge.com
Device Trade Name:	SIGNA PET/MR
Common / Usual Name:	Magnetic Resonance Diagnostic Device / Positron Emission Tomography (PET) System
Classification Name:	Emission Computed Tomography System 21 CFR 892.1200
Product Code:	OUO
Predicate Device(s):	SIGNA PET/MR (K163619)
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 detachable 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 a transmit/receive whole body radiofrequency coil. The system includes patient adaptable RF shimming capabilities. The SIGNA PET

	detectors are integrated into the MR bore. This allows for simultaneous, precisely aligned whole body MR and PET acquisitions. The PET subsystem supports Time of Flight (ToF) coincidence detection. 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. The modifications to this system include the MotionFree Brain software feature, which allows users the flexibility to correct patient head motion using the acquired PET data from the exam, without the need of external tracking devices, additional MR data, or other motion tracking data schemes.
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 Technological Characteristics:	The SIGNA PET/MR with the proposed software feature employs the same fundamental technology as the predicate device. The SIGNA PET/MR has been modified to include the MotionFree Brain feature. The user interface provides operators of the system with an option for enabling this feature. MotionFree Brain derives head motion information from the PET data; there is no need for external tracking devices, additional MR data, or additional PET data collection. The feature measures and incorporates the rigid-body motion information into the PET reconstruction, correcting the position of each coincidence event to account for patient head motion. These technological differences do not raise any different questions regarding safety and effectiveness. Both devices must allow for an effective method to setup an appropriate scan prescription. The performance data described in this submission include results of both bench testing and clinical testing that show the performance of the SIGNA PET/MR compared to the predicate device.
Summary of Nonclinical Testing:	The following quality assurance measures were applied to the development of the device: • Risk Analysis • Requirements Reviews • Design Reviews • Verification (functional testing for subsystem and system integration) • Validation (simulated use testing) 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 feature was developed under quality assurance Design Controls. Performance testing on phantoms as part of non-clinical testing demonstrated MotionFree Brain achieved performance claims for Quantitation, Temporal Resolution, and Spatial Accuracy.

	Verification documents, validation documents, and test reports have been provided for more details. Testing demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device. No new questions of safety and effectiveness were raised during nonclinical testing.
Summary of Clinical Testing:	An external reader evaluation study was performed for MotionFree Brain. The retrospective blind study involved board-certified readers who were asked to evaluate randomly labeled cases that were reconstructed with and without MotionFree Brain. The readers were blinded to feature use (e.g. whether feature was enabled or disabled), report case history, as well as to the assessments made by the other readers. The readers were asked to complete an assessment, including additional commentary, and report their preference on the pair of image series presented. Clinical testing confirms that MotionFree Brain can be used safely and effectively in a clinical setting.
Conclusion Drawn from Performance Testing:	The SIGNA PET/MR with the modified software feature has the same intended use as the predicate. This 510(k) submission includes information on the technological characteristics of the proposed software feature, as well as performance data demonstrating that the feature is as safe and effective as the predicate, and does not raise different questions of safety and effectiveness. In conclusion, GE Healthcare considers the SIGNA PET/MR to be at least as safe and effective, and its performance is substantially equivalent to the predicate device.