GE Medical Systems, LLC
% Lee Bush
Regulatory Affairs Manager
3000 N. Grandview Blvd.
WAUKESHA WI 53188

April 11, 2018

Re: K180318
Trade/Device Name: PET Digital Gating
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 2, 2018
Received: February 5, 2018

Dear Lee Bush:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180318

Device Name
PET Digital Gating

Indications for Use *(Describe)*
PET Digital Gating generates a respiratory signal which can be used to automate motion correction of PET images with respiratory motion. Images that are motion-corrected using PET Digital Gating are intended to aid physicians in: detection; localization: evaluation; diagnosis; staging; restaging; monitoring; and/or follow up of disease, abnormality, and/or function; therapy planning, monitoring, and guidance; radiotherapy treatment planning; and for Nuclear Medicine interventional procedures. PET Digital Gating maybe used with PET radiopharmaceuticals approved by the regulatory authority in the country of use, in patients of all ages, with a wide range of sizes, body habitus, and extent/type of disease.

Areas of the body most impacted by respiratory motion are the chest, abdomen, and pelvis. Disease types in which respiratory motion may have a significant impact, if uncorrected, include:

-Lung Cancer (e.g. Small Cell and Non-Small Cell);
-Liver Cancer;
-Colorectal Cancer;
-Lymphoma (e.g. Hodgkin's and Non-Hodgkin's);
-Cancers that have metastasized to the liver;
-Cancers in the Thorax; and
-Heart Disease

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 OF SAFETY AND EFFECTIVNESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h):

Date:	February 2, 2018
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Lee Bush Regulatory Affairs Manager Phone 262-309-9429 Email: Lee.Bush@ge.com
Secondary Contacts:	John Jaeckle Chief Regulatory Affairs Engineer GE Healthcare Tel: 262-424-9547 Email: john.jaeckle@ge.com
Device Trade Name:	PET Digital Gating
Common/Usual Name	PET/CT Imaging System
Classification Names	Emission Computed Tomography System per 21CFR 892.1200
Device Classification	Class II
Product Code:	KPS
Predicate Device(s):	GE Discovery MI (K161574)
Reference Devices:	Varian RPM Respiratory Gating System (K102024)

Introduction

The new PET Digital Gating option (aka Data Driven Gating or DDG) is a software-only device created within an update to the existing PET/CT acquisition and processing software. DDG provides the capability to derive a respiratory signal from the acquired PET data as an alternative to existing device-based respiratory gating options that are available on the predicate device, GE's Discovery MI (K161574). The respiratory triggers generated by PET Digital Gating are used in a manner identical to those generated by device-based respiratory gating systems such as the reference device, Varian's "RPM Respiratory Gating System" (K102024).

Intended Use

PET Digital Gating is intended to be used to detect and characterize respiratory motion using acquired PET coincidence data without the use of an external gating device.

Indications for Use

PET Digital Gating generates a respiratory signal which can be used to automate motion correction of PET images with respiratory motion. Images that are motion-corrected using PET Digital Gating are intended to aid physicians in: detection; localization; evaluation; diagnosis; staging; restaging; monitoring; and/or follow up of disease, abnormality, and/or function; therapy planning, monitoring, and guidance; radiotherapy treatment planning; and for Nuclear Medicine interventional procedures. PET Digital Gating maybe used with PET radiopharmaceuticals approved by the regulatory authority in the country of use, in patients of all ages, with a wide range of sizes, body habitus, and extent/type of disease.

Areas of the body most impacted by respiratory motion are the chest, abdomen, and pelvis. Disease types in which respiratory motion may have a significant impact, if uncorrected, include:

- *Lung Cancer (e.g. Small Cell and Non-Small Cell);*
- *Liver Cancer;*
- *Colorectal Cancer;*
- *Lymphoma (e.g. Hodgkin's and Non-Hodgkin's);*
- *Cancers that have metastasized to the liver;*
- *Cancers in the Thorax; and*
- *Heart Disease*

Background

Due to the long duration of data acquisition required to produce diagnostic quality PET images, respiratory motion has the potential to negatively impact the image quality and quantitation capability. Respiratory motion during PET imaging can degrade lesion localization and quantification (SUV and Volume) as well as cause significant artifacts, leading to reduced image quality. These effects are particularly significant during imaging of the thorax and abdomen where respiratory motion typically has the largest magnitude. The effect of respiratory motion in PET images is a loss of sensitivity in the detection of disease because of the loss in feature conspicuity and reduced quantitation accuracy associated with motion induced blurring.

A moving lesion can be expected to have a larger apparent size (volume), and lower intensity and lower SUVs.

Device Description and Technological Characteristic

PET Digital Gating provides the analogous respiratory triggers as the device-based systems, without the use of an external respiratory gating device and is an alternative to any existing external device. PET Digital Gating may be used both retrospectively on previously acquired exams, or prospectively where it operates during the acquisition. As is the case for existing device-based respiratory gating systems, PET Digital Gating's triggers may be used with GE's existing motion compensation techniques (gated, Q.Freeze, Q.Static).

Device-based systems rely on external body motion to determine the respiratory waveform. With PET Digital Gating the respiratory motion determined from internal patient anatomical movement.

PET Digital Gating uses an algorithm that incorporates a principal components analysis (PCA) to compute the spatial-temporal variation of PET list data. Principal components analysis is a data processing technique to find a mathematical basis for a dataset where the basis vectors are ordered to explain the maximum variation within the data. The PCA computes the basis vectors (eigenvectors) of the input data variation. The largest principal components are used along with the input data to generate 1-dimensional eigenvectors. These eigenvectors are subsequently used along with the list data to generate respiratory waveforms.

A fast Fourier transforms of the waveforms are used to determine an "R-value" that is used as the characterization metric for the respiratory motion identified in the dataset.

The R value threshold is user configurable. When DDG is used prospectively in conjunction with Q.Static motion correction, the R value threshold can be set for each bed position along with a "base" (no motion) acquisition time and a "Q.Static" (motion detected) acquisition time. Then, for each bed position, PET Digital Gating will evaluate the R value near the end of the base acquisition time, and if it is greater than the preset R value threshold, extend the acquisition time to the Q.Static acquisition time and generate the respiratory triggers to be used. If the evaluated R value is below the preset value, the acquisition completes and the next bed position is acquired.

In addition to not having to set up an external gating system, the benefit of PET Digital Gating to the clinician and the patient is that the clinician is no longer required to "guess" which bed positions would benefit from motion correction during exam setup and then incur the associated longer acquisition time. PET Digital Gating will assess each bed position and only extended scan time for those bed positions that could benefit from motion correction. It will also identify and apply motion correction for bed positions that that were not thought in need of motion correction during exam set up.

The PET Digital Gating software is portable and could also be made available on additional GE PET based systems (e.g. PET/CT, PET/MR, and standalone) or as a remote application on an AW Workstation/Server, cloud application, or other software platform that hosts advanced image processing applications. The primary consideration for the deployment of this feature is that the host platform can receive and process PET coincidence data (List Mode).

Comparisons

The main change in the proposed device for this submission is the addition of the PET Digital Gating option which serves as an alternative to existing device-based respiratory gating options that are available on the predicate device. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Specification/ Attribute	**Discovery MI (Predicate Device, K161574) including a third-party respiratory gating system**	**PET Digital Gating (Proposed Device)**
Gating hardware	Dedicated gating hardware required	No additional hardware required
Breathing rates	Able to be used with a wide range respiratory rates encountered clinically.	Same
Compatible motion compensation techniques able to utilize respiratory triggers	Gated, Q.Static, and Q.Freeze	Same
Reference protocols for respiratory gating	Reference protocols provided on the system	Same
Respiratory amplitude	Device-based systems rely on external body motion to determine the respiratory waveform	Respiratory motion determined from internal patient anatomical movement
Setup of gating device	Users are required to interact with the external gating device for setup	No direct user interaction
Triggering operating principle	Triggers generated based on an external patient movement as “observed” and determined by external device hardware and software	Triggers generated utilizing software algorithm (PCA) for evaluating motion of internal anatomy visualized in the PET image data
PET acquisition duration	Fixed prior to PET exam acquisition at time of prescription	Variable during PET acquisition as determined by level of respiratory motion detected

PET Digital Gating does not introduce any new risks/hazards, warnings, or limitations. The PET Digital Gating software is a "Moderate" level of concern.

Determination of Substantial Equivalence

Engineering bench testing was performed to support substantial equivalence and the product performance claims. The testing uses the commercially available respiratory motion phantom which is designed to move cylindrical inserts (activity filled spheres) in the superior/inferior direction within a body shaped oval both varying speed and amplitude. The motion of the insert is linked to a moving chest wall platform designed to carry a respiratory tracking device. Clinically determined, patient-specific respiratory motion waveforms are used to drive the phantom controller.

The testing was performed using a representative sample of each of the current GE PET/CT scanner platforms.

Representative clinical examples, where retrospective application of PET Digital Gating was used, were quantitatively analyzed to corroborate the engineering testing in support of substantial equivalence.

PET Digital Gating has successfully completed the required design control testing per GE's quality system. No new hazards were identified and no unexpected test results were obtained. PET Digital Gating was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures have been applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Software Development Lifecycle
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The testing and results did not raise different questions of safety and effectiveness than associated with predicate device using device-based respiratory gating.

Conclusion:

The Substantial Equivalence of PET Digital Gating has been demonstrated by:

- Review of the proposed labeling included in this 510k and comparison and review of the proposed Indications for Use demonstrate that PET Digital Gating's Indications for Use fall

within the intended use of the predicate device and, therefore PET Digital Gating has the same intended use as the predicate device.

- The device description and implementation details and the comparison of device characteristics show that PET Digital Gating has some technical characteristics that remain the same, such as the outputted gating signals, but different technological characteristics for how the final signals are determined.
  - That the different technological characteristics do not raise different question of safety and effectiveness than the predicate and reference devices, and that the device is as safe and effective the legally marketed predicate device as demonstrated by the:
    - submitted scientific information, including references to peer reviewed published information regarding the use of principle components analysis;
    - software verification and validation without unexpected results;
    - development under GE's quality management system, design control activities including risk management;
    - engineering bench testing using established methods and without unexpected results; and
    - supporting clinical examples that corroborate the results of the engineering bench testing.

GE Healthcare believes that the PET Digital Gating is substantially equivalent to the predicate device, Discovery MI, with supporting evidence and comparisons with its reference device, and hence is safe and effective for its intended use.