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

August 11, 2016

GE Medical Systems, L.L.C.
% Ms. Helen Peng
Regulatory Affairs Manager
3000 N Grandview Blvd.
WAUKESHA WI 53188

Re: K161574
Trade/Device Name: Discovery MI
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK
Dated: June 6, 2016
Received: June 7, 2016

Dear Ms. Peng:

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

Indications for Use

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

510(k) Number *(if known)*
K161574

Device Name
Discovery MI

Indications for Use *(Describe)*
The GE Discovery MI is a PET/CT system for producing attenuation corrected PET images. It is intended to be used by qualified health care professionals for imaging the distribution and localization of any positron-emitting radiopharmaceutical in a patient, for the assessment of metabolic (molecular) and physiologic function in patients, with a wide range of sizes and extent of disease, of all ages.

Discovery MI is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The images produced by the system may be used by physicians to aid in radiotherapy treatment planning, therapy guidance and monitoring, and in interventional radiology procedures. The images may also be used for precise functional and anatomical mapping (localization, registration, and fusion).

When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the raw and image data is an aid in; detection, localization, evaluation, diagnosis, staging, restaging, monitoring, and/or follow up, of abnormalities, lesions, tumors, inflammation, infection, organ function, disorders, and/or disease, such as, but not limited to, those in oncology, cardiology, and neurology. Examples of which are:

Cardiology:
- Cardiovascular disease
- Myocardial perfusion
- Myocardial viability
- Cardiac inflammation
- Coronary artery disease

Neurology:
- Epilepsy
- Dementia, such as Alzheimer’s disease, Lewy body dementia, Parkinson’s disease with dementia, and frontotemporal dementia.
- Movement disorders, such as Parkinson’s and Huntington’s disease
- Tumors
- Inflammation
- Cerebrovascular disease such as acute stroke, chronic and acute ischemia
- Traumatic Brain Injury (TBI)

Oncology/Cancer:
- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Breast Cancer
- Prostate Cancer
- Hodgkin disease
- Non-Hodgkin lymphoma
- Colorectal Cancer
- Melanoma

Discovery MI is also intended for stand-alone, diagnostic CT imaging in accordance with the stand-alone CT system's cleared indications for use.

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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Section 5: 510(k) Summary

Discovery MI

Aug 7, 2016 Update

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:	June 6, 2016
Submitter:	GE Medical Systems, LLC 3000 North Grandview Blvd Waukesha, WI 53188
Primary Contact:	Helen Peng Regulatory Affairs Manager Phone 262-424-8222 Email: Hong.Peng@ge.com
Secondary Contacts:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare Tel: 262-424-9547 Email: john.jaeckle@ge.com
Device Trade Name:	**Discovery MI**
Common / Usual Name:	PET/CT Imaging System
Classification Names	Emission Computed Tomography System per 21CFR 892.1200 Computed Tomography X-ray System per 21 CFR892.1750
Device Classification	Class II
Product Code:	90 KPS and 90 JAK
Predicate Device(s):	GE Discovery PET/CT 710 Clarity Edition (K133657)
Reference Devices:	GE Signa PET/MR (K142098) GE Discovery IQ (K141477)

Device Description:

The Discovery MI system is a PET/CT diagnostic imaging system combining a GE Positron Emission Tomography (PET) System and a GE Computed Tomography (CT) System.

The PET portion of the system uses a Lutetium-based Scintillator (LBS) detector. Scintillator crystal arrays are attached to Silicon Photo Multipliers (SiPM) to form detector units. The detector units are inherited from the reference device Signa PET/MR. Detector units are attached on a common support to form detector modules. The detector modules are arranged in a ring around the patient positioned inside of the PET gantry for detection of gamma rays generated as a result of PET radiopharmaceuticals injected into the patient.

The PET/CT system uses the full-featured multi-slice diagnostic CT subsystem with PET/CT post processing software to generate a map of the non-uniform attenuation in the patient. This attenuation map is then used for attenuation correction of the PET data. The CT image is also used for localization of the PET image in the patient anatomy by means of fusing the PET and CT images.

The Discovery MI system's major components are the PET gantry/detector, Revolution EVO CT system, patient table, operator console/workspace, computing hardware, power distribution unit, system software, and reconstruction software. The operator console and software provide control of the imaging (i.e. setting and confirming conditions of operation), image acquisition, dose display, reconstruction, viewing, post processing analysis, patient management, networking, and filming. The system may include respiratory and cardiac gating capabilities, signal analysis and display equipment, patient and equipment supports, components and accessories. In addition to being installed as a complete PET/CT system, the Discovery MI may result from an upgrade to a Revolution EVO- based Discovery PET/CT 710.

The Discovery MI system provides scalable axial coverage for the PET detector. All configurations offer reference adult and pediatric protocols for both hybrid PET/CT and CT applications. The PET 3D data acquisition modes include Static, Gated, Dynamic, and Whole Body scanning. All of which can be acquired with List mode data. The system includes standard PET iterative reconstruction algorithms. Q.Clear full-convergence, regularized reconstruction is optionally available. Time of Flight (ToF) may be used for all PET reconstruction types.

The CT system is the commercially available 64-detector row Revolution Evo, which may also be used for stand-alone, diagnostic CT imaging. The CT system's acquisition modes include Axial, Cine, Helical (Volumetric), Cardiac, and Gated, for head, whole body, trauma, cardiac and vascular applications.

Intended Use:

The Discovery MI PET/CT system is intended for CT attenuation corrected, anatomically localized PET imaging of the distribution of positron-emitting radiopharmaceuticals. It is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The system is also intended for stand-alone, diagnostic CT imaging.

Indications for Use:

The GE Discovery MI is a PET/CT system for producing attenuation corrected PET images. It is intended to be used by qualified health care professionals for imaging the distribution and localization of any positron-emitting radiopharmaceutical in a patient, for the assessment of metabolic (molecular) and physiologic function in patients, with a wide range of sizes and extent of disease, of all ages.

Discovery MI is intended to image the whole body, head, heart, brain, lung, breast, bone, the gastrointestinal and lymphatic systems, and other organs. The images produced by the system may be used by physicians to aid in radiotherapy treatment planning, therapy guidance and monitoring, and in interventional radiology procedures. The images may also be used for precise functional and anatomical mapping (localization, registration, and fusion).

When used with radiopharmaceuticals approved by the regulatory authority in the country of use, the raw and image data is an aid in; detection, localization, evaluation, diagnosis, staging, restaging, monitoring, and/or follow up, of abnormalities, lesions, tumors, inflammation, infection, organ function, disorders, and/or disease, such as, but not limited to, those in oncology, cardiology, and neurology. Examples of which are:

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- Movement disorders, such as Parkinson's and Huntington's disease
- Tumors
- Inflammation
- Cerebrovascular disease such as acute stroke, chronic and acute ischemia
- Traumatic Brain Injury (TBI)

Oncology/Cancer:

- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Breast Cancer
- Prostate Cancer
- Hodgkin disease
- Non-Hodgkin lymphoma
- Colorectal Cancer
- Melanoma

Discovery MI is also intended for stand-alone, diagnostic CT imaging in accordance with the stand-alone CT system's cleared indications for use.

Technological Characteristics

Discovery MI employs the same fundamental scientific technology, basic design, construction, materials, energy source, control mechanism, operating principles as the predicate device and the reference devices.

PET Detectors: The Discovery MI detector is comprised of detector units that include a LYSO Scintillator and a SiPM. These detectors have the same operating principle as the predicates and are the same as those on the Signa PET/MR reference device.

Scalable axial field of view (FOV) architecture: The Discovery MI has a scalable architecture that supports multiple axial FOVs using the same fundamental design found on the Discovery IQ reference device.

Image reconstruction: Discovery MI's image reconstruction subsystem includes updated, more powerful computational hardware to support faster reconstruction speeds and the increased datasets from larger axial FOVs and the ability for larger image pixel matrixes. There are not any new reconstruction algorithms.

Determination of Substantial Equivalence:

Discovery MI has been tested and certified to comply with IEC 60601-1 Ed. 3.0 and applicable collateral and particular standards (e.g. IEC 60601-1-2, 60601-2-44), 21CFR 1020.30 and 1020.33, DICOM, NEMA NU2-2012, NEMA XR-25, and NEMA XR-28.

Discovery MI has successfully completed the required design control testing per our quality system. No new hazards were identified and no unexpected test results were obtained. The Discovery MI 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)

GE believes Discovery MI system is of comparable type and substantially equivalent to Discovery PET/CT 710. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

The submission follow's FDA's December 3, 1998 Guidance for pre-market submission of NM, SPECT, and PET 510(k)s.

Summary of Additional Testing

In addition to standards certification testing and quality system verification testing, additional engineering testing (i.e. non-clinical testing) was performed to provide the data to: substantiate product performance and claims; establish that the device is substantially equivalent to the predicate device; and demonstrate that the device is as safe and as effective as legally marketed devices.

The testing and results do not raise different questions of safety and effectiveness than the predicate device.

Non-Clinical Testing

The additional engineering performance evaluation testing used a variety of test methods and phantoms appropriate for the performance metric/claim to be tested and evaluated. Mathematical and physics analysis were performed to demonstrate that each performance metric/claim was successfully verified and substantiated.

The items additionally evaluated for the non-clinical testing included sensitivity, NECR, resolution, and lesion detectability. The lesion detectability evaluation included a model observer study.

Product performance and claims have been substantiated via scientific, established / standardized, engineering and physics-based performance testing.

Clinical Testing

Discovery MI is designed and built from existing and cleared systems, sub-system, components, and technologies of its Predicate Device (Discovery PET/CT 710) and those found on its reference devices, (Signa PET/MR and Discovery IQ).

The difference between various ring configurations of Discovery MI all constitute only an increase in size of the PET detector, while keeping the identical detector material, construction, performance, resolution, pitch, etc. This type of change supports using scientific, established/standardized, engineering/physics-based performance testing,

without inclusion of clinical images, to demonstrate that the device is as safe and as effective as the predicate and reference devices.

Given the above information and the type and scope of the changes, particularly that the new system uses PET detector modules from the cleared Signa PET/MR, and that its 510k included numerous clinical images, clinical testing is not required to demonstrate that the Discovery MI is as safe and as effective as the legally marketed predicate and reference devices.

Conclusion:

Given that:

- The updated Indications for Use fall within the predicate device's intended use, do not raise new safety and effectiveness questions or issues, and does not represent any new intended uses.
- Discovery MI has been tested and certified to comply with the standards above identified.
- Verification testing along with additional advanced engineering testing demonstrated the Discovery MI's equivalent or superior performance to currently marketed PET/CT devices and is therefore as safe and effective.
- The changes and testing did not raise new or different questions of safety and effectiveness, and no new hazards were created.

GE Healthcare believes that the Discovery MI is substantially equivalent to the predicate device, Discovery PET/CT 710, with supporting evidence and comparisons with its reference systems; Discovery IQ and Signa PET/MR, and hence is safe and effective for its intended use.