GE Medical Systems, LLC.
% Ms. Laura Turner
Regulatory Affairs Leader
3000 North Grandview Blvd
WAUKESHA WI 53188

Re: K211846
Trade/Device Name: Discovery MI Gen2
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 14, 2021
Received: June 15, 2021

Dear Ms. Turner:

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
Thalia T. Mills, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211846

Device Name
Discovery MI Gen2

Indications for Use *(Describe)*
The GE Discovery MI Gen2 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 Gen2 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’s disease
• Non-Hodgkin’s lymphoma
• Colorectal Cancer
• Melanoma

Discovery MI Gen2 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K211846

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 14, 2021

Submitter: GE Medical Systems, LLC
3000 North Grandview Blvd
Waukesha, WI 53188

Primary Contact: Laura Turner
Regulatory Affairs Leader
GE Healthcare
Phone 262-200-1044
Email: laura.turner@ge.com

Secondary Contacts: John Jaeckle
Chief Regulatory Affairs Strategist
GE Healthcare
Tel: 262-424-9547
Email: john.jaeckle@med.ge.com

Helen Peng
Regulatory Affairs Director
GE Healthcare
Email: hong.peng@med.ge.com

PRODUCT IDENTIFICTION

Device Name: Discovery MI Gen 2
Also marketed as Discovery MI, Discovery MI Gen2, Discovery Max and Discovery Max+

Regulation number/ Product Code Emission Computed Tomography System per 21CFR 892.1200
Computed Tomography X-ray System per 21 CFR892.1750 / 90 KPS and 90 JAK

Device Classification	Class II

Predicate Device Information:

Device Name	Discovery MI
Manufacturer	GE Medical System, LLC. 3000 North Grandview Blvd Waukesha, WI 53188
510(k) number	K161574 cleared on August 11, 2016
Regulation number /product Code	Emission Computed Tomography System per 21CFR 892.1200 Computed Tomography X-ray System per 21 CFR892.1750 / 90 KPS and 90 JAK

Device Description:

GE's Discovery MI (DMI) Gen2, same as the unmodified predicate device, is a hybrid digital PET/CT diagnostic imaging system combining a GE Positron Emission Tomography (PET) System and a GE Computed Tomography (CT) System. The DMI Gen2 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.

GE has modified the cleared Discovery MI (K161574) within our design controls to include a 6-ring configuration that provides 30 cm Axial Field of View (AFOV) coverage. DMI Gen2 employs the same detector design architecture and manufacturing process as in the predicate to offer scalable ring configurations (3-ring, 4-ring, 5-ring and 6-ring) to have scalable AFOV coverage (15cm, 20cm, 25cm and 30cm) and corresponding imaging performances.

The introduction of the 30 cm configuration comes with several clinical benefits. The higher AFOV coverage, compared to other Discovery MI configurations, allows a patient to be scanned using fewer field of views, which could allow for scanning in shorter time. Additionally, sensitivity of the 30 cm system is higher compared to other configurations, like the Discovery MI 25 cm, which assists in dose reduction and better detectability of small lesions. These claims are not clinical instructions/recommendations to a physician on how their patient(s) should be scanned. Rather, they are system imaging performance-related claims.

This modified system has the same intended use and indications for use as its predicate device. The modified system employs the same basic fundamental operating principles as the existing marketed product Discovery MI, and is of comparable type and substantially equivalent to its predicate device.

Intended Use

The Discovery MI Gen2 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 Gen2 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 Gen2 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:

<u>Cardiology:</u>

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

<u>Neurology:</u>

- 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's disease
- Non-Hodgkin's lymphoma
- Colorectal Cancer
- Melanoma

Discovery MI Gen2 is also intended for stand-alone, diagnostic CT imaging in accordance with the stand-alone CT system's cleared indications for use

Technology

Discovery MI Gen2 employs the same basic operating principles and fundamental technologies as the predicate device.

The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device:

Specification/ Attribute	**Predicate Device** **Discovery MI K161574**	**Proposed Device**
PET Gantry	Multiple detector ring size configurations (15, 20, 25 cm axial FOV)	Multiple detector ring size configurations (15, 20, 25, **30** cm axial FOV).
Detector Unit	SiPM-based light sensor with ASIC	Same
	LYSO scintillator crystal	**LYSO or LGSO** scintillator crystals
CT System	Revolution EVO - Full suite of cleared CT application software with modifications (K131576)	Revolution EVO - Full suite of cleared CT application software with modifications **including Deep Learning Image Reconstruction (DLIR) K193170**
Whole Body Dynamic Acquisition (WBDA)	Whole body dynamic acquisition capability enabled by manually performing multiple passes that are also referred as static scans of a patient	Whole body dynamic acquisition capability with **automation to help the user to perform the scan with adequate user interface and dedicated tools to improve the user experience**
AutoIN	-	**Allows the operator to move the patient table from the operator console within the operator room, rather than from the gantry control panel for landmarking**

Determination of Substantial Equivalence

Discovery MI Gen2 has completed testing and is in compliance with IEC 60601-1 Ed. 3, 21CFR Subchapter J, and NEMA XR-25, XR-26, XR-28 and XR-29. The proposed device has successfully completed all testing per our quality system as well as comparison testing to the predicate device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

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

GE believes the Discovery MI Gen2 system is of comparable type and substantially equivalent to our currently marketed system Discovery MI (K161574).

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing

A broad range of engineering testing following GEHC's quality management system has been completed to demonstrate that the design outputs of the proposed device meet the design inputs, and the changes as compared to the predicate device do not raise new questions about safety and effectiveness.

In addition to the standards certification testing and system verification and validation testing successfully completed, additional engineering (non-Clinical testing) was performed to provide the requisite data to substantiate performance claims and ultimately substantial equivalence to the legally marketed predicate device.

Non-Clinical Testing

Image Performance evaluation testing used a variety of test methods and phantoms covering a broad base of relevant imaging performance and image quality test cases that demonstrate Discovery MI Gen2's ability to provide diagnostic and clinically relevant images across the full range of its expected use cases and patient populations. Mathematical and physics analysis

were performed to demonstrate that each performance claim was successfully verified and substantiated.

All testing was performed using scientific methods that are standardized (e.g. NEMA, FDA Guidance), well established, and/or reviewed in previous GE's PETCT or Nuclear Medicine clearances.

Clinical Testing

Discovery MI Gen2 is designed and built entirely from existing and cleared systems, sub-systems, components, and technologies of its Predicate Device (Discovery MI).

This type of change in Discovery MI Gen 2 is supported 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 devices.

Given the above information and the type and scope of the changes, particularly the addition of the 30 cm, 6-ring, AFOV configuration, clinical testing is not required to demonstrate that the Discovery MI Gen 2 is as safe and as effective as the legally marketed predicate device.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering testing provided, GE Healthcare believes that the Discovery MI Gen2 is as safe and effective, and performs in a substantially equivalent manner to the predicate device Discovery MI (K161574).