September 2, 2022

GE Healthcare
% Alexandra Lifshits
Regulatory Affairs Program Manager
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

Re: K221932
Trade/Device Name: Omni Legend
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, JAK
Dated: June 29, 2022
Received: July 1, 2022

Dear Alexandra Lifshits:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*

K221932

Device Name
Omni Legend

Indications for Use *(Describe)*

The GE Omni Legend 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.

Omni Legend 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
Omni Legend 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.

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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:	June 29, 2022
Submitter:	GE Medical Systems Israel, Functional Imaging (GE Healthcare) 4 Hayozma Street Tirat Hacarmel, 30200, Israel
Primary Contact:	Alexandra Lifshits Regulatory Affairs Program Manager GE Medical Systems Israel, Functional Imaging Tel: +972-4-8563666 ext. 805 Fax: +972-4-8577662 email: alexandra.lifshits@ge.com
Secondary Contacts:	John Jaeckle Chief Regulatory Affairs Engineer and Strategist GE Healthcare Tel: 262-424-9547 Email: john.jaeckle@med.ge.com
Device Trade Name:	Omni Legend
Device Classification	Class II
Regulation number:	21CFR 892.1200 and 21CFR 892.1750
Product Code	90 KPS and 90 JAK

Predicate Device Information	
Device Name	Discovery MI Gen2
Manufacturer	GE Medical System, LLC.
510(k) number	K211846
Regulation number	21CFR 892.1200 and 21CFR 892.1750
Product Code	90 KPS and 90 JAK
Reference Device Information	
Device Name	Discovery MI

Manufacturer	GE Medical System, LLC.
510(k) number	K161574
Regulation Number	21CFR 892.1200 and 21CFR 892.1750
Product Code	90 KPS and 90 JAK

Reference Device Information	
Device Name	Discovery IQ
Manufacturer	GE Medical System, LLC.
510(k) number	K141477
Regulation number	21CFR 892.1200 and CFR892.1750
Product Code	90 KPS and 90 JAK

Marketed Devices

Omni Legend is an evolution of the predicate device Discovery MI Gen2 in terms of sensitivity and spatial resolution. The primary changes are related to introducing a digital Bismuth Germanium Oxide (BGO) based PET system. The CT system is upgraded to the commercially available GE Revolution Maxima CT (K192686). The PET/CT software inherits the software functionalities available on the predicate device, is updated to support the hardware changes, and to bring enhancements, which include Auto Attenuation Correction QC (ACQC), RadRx 2.0, and Express Mode.

Device Description

GE's Omni Legend is a hybrid digital PET/CT diagnostic imaging system combining a GE Positron Emission Tomography System and the commercially available GE Revolution Maxima CT System, for excellent, best-in-class imaging performance. Omni Legend 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. It is also intended for stand-alone, diagnostic CT imaging.

Omni Legend's major components include the PET system, Revolution Maxima CT system, patient table, operator console, computing hardware, power distribution unit (PDU), system software, and reconstruction software.

The **PET System** uses the same design elements used in the predicate Discovery MI Gen2, including use of digital detection (SiPMs). The most significant difference is that the digital detection on Omni Legend uses BGO as a scintillator instead of the Lutetium-based scintillator (LYSO/LGSO) used on Discovery MI Gen2. Omni Legend's digital BGO-based detection achieves the very high sensitivity desired. The Discovery IQ reference device also uses BGO as the scintillator material for its analogic detection. Omni Legend's PET system offers scalable ring configurations (3-ring and 6-ring) to have

scalable Axial Field of Views (AFOV) of 16 and 32 cm respectively, with corresponding imaging performances.

The **CT System** is GE's commercially available 64 detector row Revolution Maxima, which may also be used for standalone, diagnostic CT imaging.

The **Operator Console** and **System Software** control image acquisition and reconstruction, image display and post processing analysis, protocol and patient management, CT dose display, networking, filming, etc. The software carries over functionalities available on the Discovery MI Gen2 product line and is updated to support the changes introduced with Omni Legend and to bring enhancement, including ACQC, RadRx 2.0, and Express Mode.

The **Patient Table** and **PDU** are identical to those of the predicate Discovery MI Gen2.

Intended Use

The Omni Legend 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 Omni Legend 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.

Omni Legend 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*

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

Technological Characteristics

Omni Legend employs the same basic operating principles and fundamental technologies as the predicate Discovery MI Gen2. The table below summarizes the substantive feature/technological differences between the predicate device and the proposed device.

Specification / Attribute	**Predicate Device:** **Discovery MI Gen2 (K211846)**	**Proposed Device:** **Omni Legend**
PET Gantry	Multiple detector ring configurations (15, 20, 25 cm axial FOV) 70 cm bore	Multiple detector ring configurations (16, 32 cm axial FOV). 70 cm bore
Detector Unit	SiPM-based light sensor with ASIC	SiPM-based light sensor with ASIC
	LYSO or LGSO scintillator crystal	BGO scintillator crystals
CT System	Revolution EVO (64 detector row) - K131576	Revolution Maxima (64 detector row) - K192686
Standards Conformance	IEC 60601-1 and applicable Collateral and Particular Standards.	IEC 60601-1 and applicable Collateral and Particular Standards.
Software Level of Risk	Moderate	Moderate

Omni Legends's technological characteristics do not create new questions of safety or effectiveness, and did not introduce any new risks/hazards, warnings, or limitations.

Determination of Substantial Equivalence

Summary of Non-Clinical, Design Control Testing

Omni Legend has successfully completed the design control testing per our quality system. No additional hazards were identified, and no unexpected test results were observed. Omni Legend was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. GE believes that the extensive bench testing and the physician evaluations performed are sufficient for FDA's substantial equivalence determination.

Omni Legend has been independently tested and conforms with IEC 60601-1 and its applicable Collateral and Particular Standards including IEC 60601-1-2, 60601-1-3, 60601-2-44, as well as performance testing per NEMA NU 2-2018.

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)

The testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device. GE believes the Omni Legend system is of comparable type and substantially equivalent to our currently marketed system Discovery MI Gen 2 (K211846). The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Additional Non-Clinical Testing

Engineering bench testing was performed to support substantial equivalence, demonstrate performance, and substantiate the product claims. Where applicable the testing was conducted according to NEMA NU-2-2018. This included testing for:

- System Sensitivity
- Noise Equivalent Count Rate (NECR)
- Contrast Recovery and Contrast to Noise Ratio
- Spatial Resolution
- Volume Resolution
- Lesion Detectability
- Quantitation
- Dose / Time Reduction (Acquisition and Image Quality)
- Design for Scalability

Clinical Testing

A clinical reader study using PET/CT exams acquired on Omni Legend was conducted. The exams constituted a clinically representative sample for evaluation of Omni Legend's performance. The results of the study support the determination of substantial equivalence. Each image was read by NM physicians who provided an assessment of overall diagnostic image quality using a Likert Scale. All of the physicians attested that their assessments demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion:

The changes associated with Omni Legend do not create a new Intended Use or Indications for Use and represent equivalent technological characteristics, with no changes to the control mechanisms, operating principle, and energy type. GE's quality system's design verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE Healthcare's quality system, the successful system and software verification and validation testing, conformance to standards, the additional engineering bench testing, and the clinical reader study demonstrates that Omni Legend is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.