GE Medical Systems Israel, Functional Imaging
Alexandra Lifshits
Sr. Program Manager, Regulatory Affairs
(GE Healthcare)
4 Hayozma Street
Tirat HaCarmel, WI 30200
Israel

August 8th, 2024

Re: K241665
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 10, 2024
Received: June 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Ningzhi Li -S

for
Daniel Krainak, Ph.D.
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

k241665

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.

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

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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 10, 2024

Submitter: GE Medical Systems Israel, Functional Imaging (GE Healthcare)
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Tirat Hacarmel, 30200, Israel

Primary Contact: Alexandra Lifshits
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Device Trade Name: Omni Legend

Device Classification Class II

Regulation number: 21CFR 892.1200 and 21CFR 892.1750

Product Code KPS and JAK

Predicate Device Information	
Device Name	Omni Legend
Manufacturer	GE Medical Systems Israel, Functional Imaging
510(k) number	K221932
Regulation number	21CFR 892.1200 and 21CFR 892.1750
Product Code	KPS and JAK

Reference Device Information	
Device Name	Precision DL
Manufacturer	GE Medical Systems Israel, Functional Imaging
510(k) number	K223212
Regulation Number	21CFR 892.1200
Product Code	KPS

Reference Device Information	
Device Name	Discovery MI
Manufacturer	GE Medical System, L.L.C.
510(k) number	K161574
Regulation number	21CFR 892.1200 and 21CFR 892.1750
Product Code	KPS and JAK

Marketed Devices

GE HealthCare's (GEHC) proposed **Omni Legend** device is a modification of the predicate Omni Legend device (K221932). The modification adds a new intermediate "4 Ring" 21 cm Axial Field of View (AFOV) system configuration to the predicate's "3 Ring" 16 cm and "6 Ring" 32 cm AFOV system configurations, as well as adds the "Enhanced AC" software option for the correction of image attenuation artifacts resulting from natural respiratory motion. The PET portion of the proposed **Omni Legend** uses the same design elements that are used in its predicate device. The software of the proposed **Omni Legend** is also developed from that of the predicate.

Device Description

GE HealthCare's subject **Omni Legend** device, same as the unmodified predicate device, is a hybrid digital PET/CT diagnostic imaging system combining a GEHC Positron Emission Tomography (PET) System and a current production diagnostic GEHC Computed Tomography (CT) System. The proposed **Omni Legend** is a conventional, general-purpose PET/CT system using existing technological characteristics with identical Intended Use and Indications for Use as its predicate.

Omni Legend is made available with a "6 Ring", "4 Ring", and a "3 Ring" configuration of its PET detector that correspondently provide an AFOV of 32 cm, 21cm, 16 cm. **Omni Legend**'s major components include PET gantry / detector, GEHC commercially available Revolution Maxima CT system (K192686), patient table, operator console / workspace, computing hardware, power distribution unit, system software, and image reconstruction software. 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.

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:

<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*

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

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

Specification / Attribute	Predicate Device: Omni Legend (K221932)	Proposed Device: Omni Legend
PET Gantry	Multiple detector ring configurations (16, 32 cm axial FOV).70 cm bore.	Multiple detector ring configurations (16, **21**, 32 cm axial FOV).70 cm bore
Detector Unit	SiPM-based light sensor with ASIC	SiPM-based light sensor with ASIC
	BGO scintillator crystals	BGO scintillator crystals
CT System	Revolution Maxima (K192686)	Revolution Maxima (K192686)
Image Reconstruction / Processing	Iterative Image Reconstruction, including Precision DL (K223212)	Iterative Image Reconstruction, including Precision DL (K223212). **PET Digital Gating (DDG) also known as MotionFree (K180318)** **Enhanced AC option**
Standards Conformance	IEC 60601-1 and applicable Collateral and Particular Standards.	IEC 60601-1 and applicable Collateral and Particular Standards.

Omni Legend'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)

Additional Non-Clinical Testing

Additional 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
- Quantitation
- Dose / Time Reduction (Acquisition and Image Quality)
- Design for Scalability

Testing of PET Digital Gating (K180318) verified use with Omni Legend and included substantiation of PET Digital Gating cleared performance claims. Testing of Enhanced AC included qualitative and quantitative evaluation of PET images corrected with Enhanced AC, including demonstration of improvement in lesion quantitation.

All testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device. GE believes the proposed **Omni Legend** is of comparable type and substantially equivalent to our currently marketed system Omni Legend (K221932).

Clinical Testing

A clinical reader study using PET/CT exams acquired on Omni Legend was conducted. The exams constituted a clinically representative sample for evaluating the performance of **Omni Legend**'s Enhanced AC option. 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 as well as the ability of Enhanced AC to correct artifacts. All of the physicians attested that their assessments demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion:

The modifications associated with proposed **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. GEHC'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 GEHC'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 the proposed **Omni Legend** is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.