April 27, 2023

GE Healthcare
% George Mashour
Senior Regulatory Affairs Manager
GE Medical Systems Israel
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

Re: K223212
Trade/Device Name: Precision DL
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: March 27, 2023
Received: March 29, 2023

Dear George Mashour:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K223212

Device Name

Precision DL

Indications for Use *(Describe)*

Precision DL is a deep learning-based image processing method intended to enhance image quality of non-ToF PET images for clinical oncology purpose, using F-18 FDG. Precision DL may be used for patients of all ages.

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: March 29, 2023

Submitter: GE Medical Systems Israel, Functional Imaging (GE Healthcare)
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Device Trade Name: Precision DL

Device Classification: Class II

Regulation Number: 21CFR 892.1200

Product Codes: KPS

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

Reference Device Information	
Device Name:	Discovery MI
Manufacturer:	GE Medical Systems, LLC.
510(k) Number:	K161574
Regulation Number/ Product Code:	21CFR 892.1200 & 21CFR 892.1750 KPS & JAK

Device Description

Precision DL is a deep learning-based image processing method intended for PET oncology 18F-FDG images obtained using the predicate device Omni Legend PET/CT system. Precision DL enhances the non-ToF Q.Clear images to have image quality performance similar to PET images obtained using ToF capable PET systems, including enhancement in image Contrast Recovery (CR), Contrast to Noise Ratio (CNR), and quantitation accuracy. Precision DL's training used clinical data from diverse clinical sites, accounting for relevant variations in patients and sites' protocols.

Precision DL brings three deep learning models to provide users the choice between different strengths of contrast enhancement and noise reduction. The three models, Low, Medium, and High Precision DL, are trained such that the High Precision DL brings the highest contrast enhancement and lowest noise reduction, while the Low Precision DL brings the lowest contrast enhancement and highest noise reduction. Medium Precision DL brings contrast-noise tradeoff in between High and Low Precision DL.

Precision DL is deployed within the acquisition and processing software of Omni Legend, for processing images produced using non-ToF Q.Clear image reconstruction.

Intended Use

Precision DL is a deep learning-based image processing method intended for Positron Emission Tomography images.

Indications for Use

Precision DL is a deep learning-based image processing method intended to enhance image quality of non-ToF PET images for clinical oncology purpose, using F-18 FDG. Precision DL may be used for patients of all ages.

Technological Characteristics

Precision DL is an image processing option for the predicate Omni Legend device that produces substantially equivalent images to those produced using non-ToF Q.Clear reconstruction. Since the Precision DL option is deployed within Omni Legend's acquisition and processing software, it utilizes the same hardware and software platform as the non-ToF Q.Clear reconstruction. The table below summarizes the substantive feature / technological differences between the predicate device and the proposed device:

Specification	**Predicate Device** **Omni Legend (K221932)** including non-ToF Q.Clear Image Reconstruction	**Proposed Device** **Precision DL** on Omni Legend
Technology	Iterative non-ToF image reconstruction algorithm	Deep learning-based image processing trained to enhance non-ToF images to have IQ performance similar to ToF images.

Precision DL's technological characteristics do not raise 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 Testing

Precision DL has successfully completed the design control testing per GE's quality system. No additional hazards were identified, and no unexpected test results were observed. Precision DL was designed 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.

The following quality assurance measures have been applied to the development of the system:

- Requirement Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Testing on unit level (Module verification)
- Integration testing (System verification)
- System Testing:
  - Safety Testing (Verification)
  - System and Image Performance Testing (Verification)
  - Simulating Use Testing (Validation)

Additional engineering bench testing also included testing that demonstrates performance and substantiates the product claims. The testing confirmed performance improvements over existing non-ToF Q.Clear reconstruction and compared performance to ToF reconstruction using the same data from the reference Discovery MI that has hardware-based ToF. The test datasets included both clinical and NEMA Image Quality phantom data, which was segregated, completely independent, and not used in any stage of the algorithm development, including training. The clinical data consisted of 80 PET-CT exams from multiple clinical sites in North America, Europe, and Israel. 40 exams were obtained on an Omni Legend system while the other 40 were obtained on Discovery MI systems incorporating a range of Axial Field of Views. The clinical exams spanned typical patient demographics for F-18 FDG oncological imaging with typical site-specific oncology imaging protocols, without specific inclusion / exclusion criteria. The ground truth was Discovery MI's ToF PET images and known quantitation from inserted lesions of known size, location, and contrast. The additional non-clinical testing included testing for:

- Quantitation Accuracy
- Contrast Recovery
- Contrast-to-Noise Ratio
- Lesion Detectability
- Dose / Time Reduction

All the testing and results did not raise new or different questions of safety and effectiveness than associated with predicate device. We consider the proposed device is substantially equivalent to the predicate device.

The substantial equivalence is also based on the software documentation for a "Moderate" level of concern. GE believes that Precision DL is of comparable type and substantially equivalent to the predicate device.

Clinical Testing

A clinical reader study using Omni Legend images processed with Precision DL was conducted at two clinical sites. The study included review by board certified radiologists to assess overall image quality of Precision DL images. The board-certified radiologists also answered blinded preference questions comparing clinical cases of the same patients obtained on Discovery MI and Omni Legend with Precision DL. The results of the reader study and preference questions support the determination of substantial equivalence. All readers attested that their assessments of Precision DL demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion

The changes associated with Precision DL do not create a new Intended Use and represent technological characteristics that produce images of equivalent diagnostic quality.

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, the additional engineering bench testing, and the clinical testing demonstrates that Precision DL is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.