January 3, 2025

GE Medical Systems Israel, Functional Imaging
% Maysana Mousa Elias
Senior Regulatory Affairs Leader
GE HealthCare
3000 N Grandview Blvd W 440
Waukesha, Wisconsin 53188

Re: K241350
Trade/Device Name: Clarify DL
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, KPS
Dated: May 13, 2024
Received: December 3, 2024

Dear Maysana Mousa Elias:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Daniel M. 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)*

K241350

Device Name

Clarify DL

Indications for Use *(Describe)*

Clarify DL is a deep learning-based image reconstruction method intended to reduce noise and improve image quality of Nuclear Medicine bone SPECT scintigraphy images. Clarify 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.

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

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K241350

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:	January 03, 2025
Submitter:	GE Medical Systems Israel, Functional Imaging (GE HealthCare) 4 Hayozma Street Tirat Hacarmel, 30200, Israel
Primary Contact:	Maysana Mousa Elias Senior Regulatory Affairs Leader GE Medical Systems Israel, Functional Imaging Tel: +972-4-8563666 Mobile: +972-54-7850710 Email: Maysana.MousaElias@gehealthcare.com
Secondary Contact:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare Tel: 262-424-9547 Email: john.jaeckle@gehealthcare.com
Device Trade Name:	Clarify DL
Device Classification:	Class II
Regulation Number:	21CFR 892.1200 & 21CFR 892.2050
Product Codes:	KPS & LLZ

Predicate Device Information

Predicate Device 1	
Device Name:	Xeleris V Processing and Review System
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K221680
Regulation Number/ Product Code:	21CFR 892.2050 / LLZ
Predicate Device 2	
Device Name:	StarGuide
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K210173
Regulation Number/ Product Code:	21CFR 892.1200 / KPS

21CFR 892.1750 / JAK

Device Description

Clarify DL is a software-only device for the reconstruction of NM bone SPECT scintigraphy images obtained using supported GE HealthCare SPECT and SPECT-CT systems. Clarify DL is designed to reduce image noise while maintaining contrast to enable increased Contrast-to-Noise Ratio (CNR) and Contrast Recovery Coefficient (CRC). Clarify DL is deployed within the software of the predicate Xeleris V Processing and Review System and StarGuide devices.

Clarify DL includes a Predetermined Change Control Plan (PCCP) with one planned modification. The modification is for making Clarify DL available for imaging data acquired using a SPECT-CT system that incorporates a different CT. Clarify DL remains unchanged and maintains the same intended use, indications for use and equivalent performance. Performance evaluation for the modification includes testing to confirm equivalence of the input CT data and that Clarify DL's overall IQ performance is maintained and substantially equivalent to its performance with imaging data from a supported SPECT-CT system. The user documentation will be updated to reflect the modification (i.e. description of new source of data, summary of release and performance evaluation).

Intended Use

Clarify DL is a deep learning-based image reconstruction method intended for Nuclear Medicine SPECT images.

Indications For Use

Clarify DL is a deep learning-based image reconstruction method intended to reduce noise and improve image quality of Nuclear Medicine bone SPECT scintigraphy images. Clarify DL may be used for patients of all ages.

Technology Characteristics

Clarify DL is an additional image reconstruction option for the predicate Xeleris V Processing and Review System and StarGuide devices. Clarify DL produces substantially equivalent images to those produced using the predicate devices' cleared image reconstruction. Because Clarify DL is deployed within the predicate Xeleris V and StarGuide devices software, it utilizes the same hardware and software platform as their cleared image reconstruction. The tables below summarize the substantive feature / technological differences between the predicate device and the proposed device:

Specification	**Predicate Device 1** **Xeleris V Processing and Review System (K221680)**	**Proposed Device** **Clarify DL** on Xeleris V
Technology	OSEM-based Iterative Image Reconstruction	OSEM-based Iterative Image Reconstruction with integrated deep learning model trained to reduce noise

Specification	Predicate Device 2 **StarGuide (K221680)** including Smart Console	Proposed Device **Clarify DL** on StarGuide's Smart Console
Technology	OSEM-based and BSREM-based Iterative Image Reconstruction	OSEM-based and BSREM-based Iterative Image Reconstruction with integrated deep learning model trained to reduce noise

Clarify 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

CDL has successfully completed the design control testing per GEHC's quality system. No additional hazards were identified, and no unexpected test results were observed. CDL was designed under the Quality System Regulations of 21CFR 820 and ISO 13485. GEHC 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 included testing that demonstrates performance and substantiates the product claims. The testing confirmed substantial equivalent performance compared to the predicate devices' cleared image reconstruction for several acquisition settings. The testing included testing for image and lesion level characteristics, as follows:

- **Image level testing** included testing for Structure Similarity Index Measure (SSIM), Mean Squared Error (MSE), and Peak Signal-to-Noise Ratio (PSNR)
- **Lesion level testing** included testing for Contrast-to-Noise ratio (CNR) and Contrast Recovery Coefficient (CRC).

The additional engineering bench testing substantiated all performance claims. All the testing and results did not raise new or different questions of safety and effectiveness than associated with predicate devices. GEHC considers that the proposed Clarify DL device is of comparable type and substantially equivalent to the predicate devices.

Summary of Clinical Testing

The clinical testing included a clinical reader evaluation of clinical bone SPECT and SPECT-CT exams obtained using supported SPECT CT systems. The clinical exams included in Clarify DL's clinical evaluation came from 11 hospitals, including 5 US hospitals from 4 different states (i.e Ohio, Kansas, Rhode Island, and California) and 6 non-US hospitals from Europe and Asia. The clinical reader evaluation included review by expert NM physicians to assess overall Image Quality, Image Resolution, and Noise Level. The results of the clinical reader evaluation support the determination of substantial equivalence. All readers attested that their assessments of Clarify DL demonstrated acceptable diagnostic results.

Substantial Equivalence Conclusion

The changes associated with Clarify DL do not change the indications for use and represent technological characteristics that produce images of equivalent diagnostic quality.

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.

Design verification, along with the bench testing and the clinical reader evaluation included in the "Performance Testing" section of this submission, demonstrate that Clarify DL is substantially equivalent to, and hence as safe and as effective for its intended use as the legally marketed predicate devices.

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