March 1, 2023

GE Healthcare
℅ George Mashour
Regulatory Affairs Manager
4 Hayozma Street
Tirat Hacarmel, 30200
ISRAEL

Re: K221680
Trade/Device Name: Xeleris V Processing and Review System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 26, 2023
Received: January 27, 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)*

K221680

Device Name

Xeleris V Processing and Review System

Indications for Use *(Describe)*

The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma cameras or PET scanners. The system can run on dedicated workstation or in a server-client configuration.

The NM or PET data can be coupled with registered and/or fused CT or MR scans, and with physiological signals in order to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in scanned body tissue for clinical diagnostic purposes.

The DaTQUANT optional application enables visual evaluation and quantification of 123I-ioflupane (DaTscanTM) images. DaTQUANT Normal Database option enables quantification relative to normal population databases of 123I-ioflupane (DaTscanTM) images. These applications may assist in detection of loss of functional dopaminergic neuron terminals in the striatum, which is correlated with Parkinson disease.

The Q.Lung AI application may aid physicians in:
-Diagnosis of Pulmonary Embolism (PE), Chronic Obstructive Pulmonary Disease (COPD), Emphysema and other lung deficiencies.
-Assess the fraction of total lung function provided by a lobe or whole lung for Lung cancer resection requiring removal of an entire lobe, bilobectomy, or pneumonectomy.

The Q.Brain application allows the user to visualize and quantify relative changes in the brain's metabolic function or blood flow activity between a subject's images and controls, which may be resulting from brain function alterations in:
-Epileptic seizures
-Dementia. Such as Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, vascular dementia, and frontotemporal dementia.
-Inflammation
-Brain death
-Cerebrovascular disease such as Acute stroke, Chronic and acute ischemia
-Traumatic Brain Injury (TBI)
When integrated with the patient's clinical and diagnostic information, Q.Brain application may aid the physician in the interpretation of cognitive complaints, neuro-degenerative disease processes and brain injuries.

The Alcyone CFR application allows for the quantification of coronary vascular function by deriving Myocardial Blood Flow (MBF) and then calculating Coronary Flow Reserve (CFR) indices on data acquired on PET scanners and on stationary SPECT scanners with the capacity for dynamic SPECT imaging. These indices may add information to physicians using Myocardial Perfusion Imaging for the diagnosis of Coronary Artery Disease (CAD).

The Exini Bone application is intended to be used with NM bone scans for the evaluation of adult male patients with bone metastases from prostate cancer. Exini Bone quantifies the selected lesions and provides a Bone Scan Index value as adjunct information related to the progression of disease.

The Q.Liver application provides processing, quantification, and multidimensional review of Liver SPECT/PET and CT images for display, segmentation, and a calculation of the SPECT 'liver to lung' shunt value and the patient's Body Surface Area (BSA) for use in calculating a therapeutic dose for Selective Internal Radiation Therapy (SIRT) treatment using a user defined formula.

The Q.Thera AI application allows physicians review and monitor patient radiation doses derived from nuclear medicine imaging data, including SPECT/CT, PET/CT, and Whole-body Planar images, and from biological samples from the patient. The application provides estimates of isotope residence time, absorbed dose, and equivalent dose at the whole organ level, as well as estimates of whole-body effective dose. The output from Q.Thera AI may aid physicians in monitoring patient radiation doses.
For use with internally administered radioactive products. Q.Thera AI should not be used to deviate from approved product dosing and administration instructions. Refer to the product's prescribing information for instructions.

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.

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K221680

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 8, 2022

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

Primary Contact: George Mashour
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Device Trade Name: Xeleris V Processing and Review System

Device Classification: Class II

Regulation Number: 21CFR 892.2050

Product Codes: LLZ

Predicate Device Information	
Device Name:	Xeleris V Processing and Review System
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K201103
Regulation Number/ Product Code:	21CFR 892.2050 LLZ

Reference Device Information	
Device Name:	Olinda/EXM v2.0
Manufacturer:	Hermes Medical Solutions AB
510(k) Number:	K163687
Regulation Number/ Product Code:	21 CFR 892.1100 IYX

Reference Device Information	
Device Name:	Xeleris 4.0 Processing and Review System
Manufacturer:	GE Medical Systems Israel, Functional Imaging
510(k) Number:	K153355
Regulation Number/ Product Code:	21CFR 892.2050 LLZ

Marketed Devices

Xeleris V Processing and Review System is a modification to the predicate Xeleris V Processing and Review System (K201103). It includes all of the clinical applications and features in the current production version of the predicate Xeleris V, and introduces two clinical applications: Q.Thera AI and Generate Planar. The Indications for Use remain the same as those of the predicate device, except for the additional indications for the Q.Thera AI application. The proposed Xeleris V indications for use do not add a new Intended Use.

Device Description

Xeleris V Processing and Review System is a Nuclear Medicine Software system that is designed for general nuclear medicine processing and review procedures for detection of radioisotope tracer uptake in the patient's body, using a variety of individual processing applications orientated to specific clinical applications. It includes all of the clinical applications and features in the current production version of the predicate Xeleris V and, introduces two clinical applications

Q.Thera AI: The Q.Thera AI application allows physicians review and monitor patient radiation doses derived from nuclear medicine imaging data, including SPECT/CT, PET/CT, and Whole-body Planar images, and from biological samples from the patient. The application provides estimates of isotope residence time, absorbed dose, and equivalent dose at the whole organ level, as well as estimates of whole-body effective dose. The output from Q.Thera AI may aid physicians in monitoring patient radiation doses.

Q.Thera AI is a modification to the predicate's Dosimetry Toolkit application for enhancing site's dosimetry workflow through the following updates:

- Image Pre-Processing: Q.Thera AI uses the predicate's Q.Volumetrix MI application for image pre-processing, bringing additional automated organ segmentations as well as enabling dosimetry on PET/CT imaging data.
- Dosimetry Calculations: Q.Thera AI adds calculation of radiation doses to Dosimetry Toolkit's previous determination of isotope residence time. Similar to the reference Olinda/EXM (K163687), the added calculations follow the guidelines published by the Medical Internal Radiation Dose (MIRD) committee of the Society of Nuclear Medicine (SNM) and models from publication Nº 89 of the International Commission on Radiological Protection (ICRP).

Generate Planar: The Generate Planar application produces 2D derived planar images from 3D SPECT images that are acquired using GE Healthcare's StarGuide SPECT-CT system (K210173). Generate Planar was first cleared on Xeleris 4.0 (K153355). It was also included in StarGuide's 510(k) clearance for producing derived planar images from hybrid SPECT-CT studies. Xeleris V brings the Generate Planar

application from Xeleris 4.0 and expands it to also produce derived planar images from SPECT-only studies.

Intended Use

The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians. The intended use of the system is to provide digital processing, review and reporting of medical images, including data display, quality control, image manipulation and quantification analysis, transfer, storage, and printing capabilities.

The system operates in a variety of configurations. The hardware components may include computer workstations, communications devices, video monitors, data storage and hardcopy devices.

Software components provide functions for performing operations related to image display, manipulation, enhancements, analysis and quantification and can operate on dedicated workstations and client-server architectures.

Indications for Use

The system is intended for use by Nuclear Medicine (NM) or Radiology practitioners and referring physicians for display, processing, archiving, printing, reporting and networking of NMI data, including planar scans (Static, Whole Body, Dynamic, Multi-Gated) and tomographic scans (SPECT, Gated SPECT, dedicated PET or Camera-Based-PET) acquired by gamma cameras or PET scanners. The system can run on dedicated workstation or in a server-client configuration.

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*The **Q.Lung AI** application may aid physicians in:*

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- *Assess the fraction of total lung function provided by a lobe or whole lung for Lung cancer resection requiring removal of an entire lobe, bilobectomy, or pneumonectomy.*

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- *Epileptic seizures*
- *Dementia. Such as Alzheimer's disease, Lewy body dementia, Parkinson's disease with dementia, vascular dementia, and frontotemporal dementia.*
- *Inflammation*

- *Brain death*
- *Cerebrovascular disease such as Acute stroke, Chronic and acute ischemia*
- *Traumatic Brain Injury (TBI)*

When integrated with the patient's clinical and diagnostic information, Q.Brain application may aid the physician in the interpretation of cognitive complaints, neuro-degenerative disease processes and brain injuries.

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Technological Characteristics

Xeleris V's basic functionality for processing and reviewing Nuclear Medicine images and their associated CT images is not changed from its predicate. This functionality includes manual and automatic segmentation to depict, localize, and/or quantify the distribution of radionuclide tracers and anatomical structures in patients for diagnostic purposes. Much of this functionality is designed for streamlined user workflows.

Xeleris V introduces the Q.Thera AI and Generate Planar applications that are focused on specific clinical imaging scenarios, using this basic functionality. Q.Thera AI and Generate Planar are both modifications to previously cleared applications:

Attributes	**Predicate Device** **Xeleris V Processing and Review System (K201103)**	**Proposed Device** **Xeleris V Processing and Review System**
Q.Thera AI Application		
Supported Input Data	- NM Imaging Data: SPECT-CT and Whole-body Planar	- NM Imaging Data: SPECT-CT, PET-CT, and Whole-body Planar - Non-Imaging Data
Image Pre-Processing Application	- Preparation for Dosimetry Toolkit	- Preparation for Dosimetry Toolkit - Q.Volumetrix MI for Q.Thera AI
Supported Dosimetry Calculations	- Organ and Lesion isotope residence time	- Organ and Lesion isotope residence time - Radiation dose calculations per MIRD committee of SNM and ICRP Publication 89
Generate Planar Application		
Derived Planar Images	Not Available	- Derived planar images from SPECT-CT studies, as cleared on the reference Xeleris 4.0. - Derived planar images from SPECT only studies.

The Xeleris V Processing and Review System has identical or equivalent technological characteristics as its predicate and reference devices. The changes and the different technological characteristics do not raise new or different questions of safety and effectiveness. The software was developed, verified, and validated under GE Healthcare's QMS including software development lifecycle.

Determination of Substantial Equivalence

Summary of Non-Clinical, Design Control Testing

The proposed Xeleris V device has successfully completed the design control testing per GE's quality system, and also verified compliance with the relevant standards (i.e. NEMA PS3.1 - 3.20, IEC62304). No additional hazards were identified, and no unexpected test results were observed. Xeleris V is designed and manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485.

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)

The testing and results did not raise new or different questions of safety and effectiveness than those associated with predicate device. GE considers the proposed device is substantially equivalent to the predicate device. The substantial equivalence is also based on software documentation for a "Moderate" level of concern. GE believes that Xeleris V is of comparable type and substantially equivalent to the predicate and reference devices.

Q.Thera AI and Generate Planar Non-Clinical Testing

Bench testing for Q.Thera AI confirmed the correctness of the resulting radiation doses across different possible combinations (e.g. models, organs, isotopes) of calculations. For Generate Planar, bench testing demonstrated similarity between derived planar images produced from SPECT only studies to derived planar images produced from SPECT-CT studies. Similarity was demonstrated using representative clinical datasets for a variety of factors that impact attenuation levels (e.g. body region, BMI).

Clinical Testing

The proposed Xeleris V did not require clinical studies to support substantial equivalence. The bench testing, including measurements on representative clinical datasets where applicable, demonstrated the outputs of the software applications to substantiate their performance

Substantial Equivalence Conclusion

The Indications for Use of the proposed Xeleris V Processing and Review System do not create a new Intended Use. Xeleris V, with the added Q.Thera AI and Generate Planar applications, has identical or equivalent technological characteristics as its predicate device. 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 modifications made to the predicate.

Based on development under GE's quality system, the successful verification testing, including the bench testing of Q.Thera AI and Generate Planar, as well as conformance to standards demonstrate that Xeleris V is substantially equivalent to, and hence as safe and as effective for its Intended Use, as the legally marketed predicate device.