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

September 25, 2020

Re: K201103
      Trade/Device Name: Xeleris V Processing and Review Systems
      Regulation Number: 21 CFR 892.2050
      Regulation Name: Picture archiving and communications system
      Regulatory Class: Class II
      Product Code: LLZ
      Dated: August 13, 2020
      Received: August 18, 2020

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
   and 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: 06/30/2020

See PRA Statement below.

510(k) Number *(if known)*

K201103

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 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.

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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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:	April 23rd, 2020
Submitter:	GE Medical Systems Israel, Functional Imaging (GE Healthcare)
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	Tirat Hacarmel, 30200, Israel
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	Chief Regulatory Affairs Strategist
	GE Healthcare
	Tel: 262-424-9547
	email: john.jaeckle@ge.com
Device Trade Name:	Xeleris V Processing and Review System
Common / Usual Name:	System, Image Processing, Radiological
Classification Names:	21CFR 892.2050
Product Code:	LLZ

Predicate Device

Device Name	Xeleris 4.0 Processing and Review Workstation
510 (K) number	K153355
Regulation №	892.2050
Product Code	LLZ

Reference	Device Name	EXINI's aBSI
Devices		
	510 (K) number	K191262
	Regulation №	892.2050
	Product Code	LLZ

	Device Name	GE's Hepatic VCAR
	510 (K) number	K133649
	Regulation №	892.1750
	Product Code	JAK, LLZ

Marketed Devices

The Xeleris V Processing and Review System is a modification to the predicate device, Xeleris 4.0 Processing and Review Workstation. It includes all of the clinical applications and features in the current production version of Xeleris 4.0 and, introduces new clinical applications (i.e. Exini Bone, Q.Liver) and enhancements to previously cleared clinical applications (i.e. Q.Lung, Myovation, Q.Volumetrix MI, Q.Brain).

Xeleris V's Indications for Use remain the same as the predicate device's except for additional indicates for the new clinical applications, Exini Bone and Q.Liver. Xeleris V's Indications for Use do not create a new Intended Use.

Device Description:

The Xeleris V Processing and Review Workstation 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.

Xeleris V is a modification to the predicate device, Xeleris 4.0 Processing and Review Workstation. It includes all the clinical applications and features in the current production version Xeleris 4.0 and introduces new clinical applications and enhancements to previously cleared clinical applications.

With Xeleris V, the customer now has an option where they can purchase the Xeleris V software, and have it installed on a remote server.

New Clinical Applications

Exini Bone: 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. The application automatically segments bone lesions based on 2D whole-body planar bone scans and requires the user adjust and/or accept the final segmentation before proceeding. Exini Bone quantifies the selected lesions and provides a Bone Scan Index value as adjunct information related to the progression of disease.

- **Q.Liver:** The Q.Liver application is a comprehensive application that provides processing, quantification, and multidimensional review of liver SPECT/CT exams for display and segmentation. The application provides the user with tools to calculate a therapeutic dose for Selective Internal Radiation Therapy (SIRT) treatment.

Enhancements to Clinical Applications

- **Q.Lung:** The Q.Lung application provides processing, quantification, and multidimensional review for pulmonary scintigraphy for display and quantification of global and regional ventilation and perfusion on SPECT and SPECT/CT studies. The change introduced in Xeleris V is the introduction of an optional lung fissure automatic detection using a Deep Learning based model.

- **Myovation:** The Myovation application is used for the evaluation of patients with suspected or known coronary artery disease. Myovation reconstructs and reformats the SPECT raw data and helps to analyze the myocardial perfusion and function in rest, stress, and viability studies. The change for Xeleris V is the introduction of a new optional, non-AI Automatic Recognition of Cardiac Structures (ARCS) algorithm for improved heart detection and orientation.

- **Q.Volumetrix MI:** The Q.Volumetrix MI application is a compressive tool for processing and reading non-cardiac volumetric data, including NM SPECT and hybrid SPECT-CT, PET-CT, external CT/MR (i.e. CT/MR from a separate non-hybrid scan). The enhancement for Xeleris V is a new, optional, DL-based automatic kidney segmentation algorithm.

- **Q.Brain:** The Q.Brain application is used to process, quantify, and review brain studies obtained that include SPECT , SPECT/CT , PET/CT, and MR datasets. Q.Brain processing includes reconstruction, reorientation, rigid registration, and non-rigid registration of single or sequential tomographic brain data. The enhancement introduced with Xeleris V is that the display of the CT images registered to the template is now included along with other currently available image types.

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.

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- Brain death
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Technology: Xeleris V's basic functionality for processing and reviewing Nuclear Medicine 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 two new applications that are focused on specific clinical imaging scenarios, using this basic functionality Xeleris V also enhances three existing applications to improve their workflow efficiency using both DL-based and traditional algorithms.

Attribute	Predicate Device: Xeleris 4.0	Proposed Device: Xeleris V
General Workflows	Xeleris 4.0's workflows use both manual and automated processes.	Xeleris V's workflows continue use both manual and automated processes. Xeleris V also includes two new, DL-based automatic segmentation algorithms.
Use of Deep Learning	Xeleris 4.0 does not contain any DL processes/algorithms.	Xeleris V introduces two new DL-based algorithms for: • Lung fissure segmentation as an alternative to the manual method. • Kidney segmentation as an enhancement to the non-DL automatic segmentation.
Hardware Needed to Support Xeleris V's software	Xeleris 4.0 offered with a GE workstation or as software that can be loaded onto the customer's workstation that meets specification.	In addition to the two options for the predicate, with Xeleris V the software can also be installed on a remote server.

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.

Testing Summary

<u>Design Control Testing:</u>

Xeleris V and its clinical applications successfully completed all design control testing per GE Healthcare's quality system and also verified compliance with the relevant standards (i.e. NEMA PS3.1 - 3.20, IEC62304). The testing did not raise any new safety questions or identify any new risks. Xeleris V is designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- SW Development Lifecycle
- Testing on Unit Level (Module Verification)

- Integration Testing (System Verification)
- Performance Testing (Verification)
- Safety testing (Verification)
- Simulated Use Testing (Validation)

The testing and their results do not raise different questions of safety and effectiveness than the predicate device. GE believes Xeleris V is of comparable type and substantially equivalent to the predicate and reference devices, and hence is safe and effective for its intended use. The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing:

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering and clinical performance testing was performed to provide the requisite data to demonstrate performance and substantiate claims. This testing included:

Engineering testing including clinical datasets and clinician participation.

- Demonstration of clinical outputs, workflow, and tools.
- Scientific testing for algorithm performance and claims substantiation.
- Algorithm clinical performance testing using test datasets of representative clinical exams where the ground truth and evaluations were performed by clinicians.

Clinical Evaluation

Xeleris V did not require clinical studies to support the determination of equivalence. However, the performance testing for the DL-based algorithms for kidney segmentation and lung fissure segmentation evaluates and demonstrates each algorithm's performance and uses test datasets of representative clinical exams.

The test datasets were comprised of representative clinical exams that were manually segmented by experienced NM Physicists and Physicians and were used as ground truth. The NM Physicists and Physicians also performed the algorithm evaluation. They reviewed the segmentation results and scored them using a 5-point Likert scale.
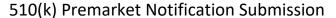
The scientific methods used to evaluate the effectiveness of Xeleris V are acceptable and support the determination of substantial equivalence.

Substantial Equivalence

The Substantial Equivalence of the proposed device has been demonstrated by:

- Review of the proposed Indications for Use shows that they are substantially equivalent to the predicate device's, also with consideration of the reference devices. Xeleris V's Indications for Use do not create a new Intended Use.

- The device description and the comparison of device characteristics show that Xeleris V's has identical or equivalent technological characteristics as its predicate and reference devices.

- The testing (engineering and clinical) demonstrates the effectivity of Xeleris V for its intended purpose.

- The changes and the different technological characteristics do not raise new or different questions of safety and effectiveness. The proposed device is as safe and effective as the legally marketed predicate device as demonstrated by the:

  o Software verification and validation for a Moderate level of concern, without unexpected results;

  o Development under GE's quality management system, design control activities including risk management;

  o Device labeling; and

  o Engineering and clinical testing without unexpected results.

Conclusion: Xeleris V's Indications for Use do not create a new Intended Use. Xeleris V has identical or equivalent technological characteristics as its predicate device.

Xeleris V was developed under GE Healthcare's quality system. Design verification testing, along with bench and clinical testing demonstrate that Xeleris V is substantially equivalent and hence as safe and as effective as the legally marketed predicate device. GE's quality system's design, verification, and risk management processes did not identify any new hazards, unexpected results, or adverse effects stemming from the changes to the predicate.

Based on development under GE Healthcare's quality system, the successful verification, engineering bench and clinical testing, GE Healthcare believes that Xeleris V is substantially equivalent to the predicate device and hence is safe and effective for its intended use.