DEPARTMENT OF HEALTH & HUMAN SERVICES   Public Health Service

_____

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare   March 16, 2016
GE Medical Systems Israel, Functional Imaging
℅ Efrat Hartog-David, Ph.D.
Regulatory Affairs Manager
4 Hayozma Street
Tirat Hacarmel 30200
ISRAEL

Re: K153355
     Trade/Device Name: Xeleris 4.0 Processing and Review Workstation
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Picture archiving and communications system
     Regulatory Class: II
     Product Code: LLZ
     Dated: February 28, 2016
     Received: March 1, 2016

Dear Dr. Hartog-David:

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. 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); good manufacturing practice requirements as set
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic
product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara   For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
 and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K153355

Device Name

Xeleris 4.0 Processing and Review Workstation

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.

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

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.

Q.Brain 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, when used with radiopharmaceuticals approved by the regulatory authority in the country of use, 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).

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.

510(k) Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date:	February 9, 2016
Submitter:	GE Healthcare, GE Medical Systems Israel, Functional Imaging 4 Hayozma St. TIRAT HACARMEL, 30200, ISRAEL
Primary Contact Person:	Efrat Hartog-David Regulatory Affairs Manager GE Healthcare, GE Medical Systems Israel, Functional Imaging +972-4-8563666 ext. 805 +972-4-8577662
Secondary Contact Person:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare 262-424-9547
Device Trade Name:	Xeleris 4.0 Processing and Review Workstation
Device Classification Name:	System, Image Processing, Radiological
Regulation number:	21CFR 892.2050
Class:	Class II
Product Code:	LLZ
Marketed devices:	The Xeleris 4.0 is a new Processing and Review Software built upon the existing technologies of the predicate device Xeleris 3.1 Processing and Review Workstation (K130884). It is of comparable type and substantially equivalent to its predicate device Xeleris 3.1. In addition, the software has the same intended use as that of the predicate device. The proposed device's indications for use have been revised to add the software capabilities as substantiated and verified in the bench and testing provided.

Predicate Device:	K130884 - Xeleris 3.1 Processing and Review workstation
Reference Devices:	K103480 - Thoracic VCAR
	K141074 - CortexID Suite
	K101279 - Corridor4DM v2010
Device Description:	The Xeleris 4.0 is a Nuclear Medicine software-only device designed for general nuclear medicine processing & review procedures for detection and quantification of radioisotope tracer uptake in the patient body, using a variety of processing modes for various clinical applications types defined by anatomy and/or function of interest, radiopharmaceuticals, NM system acquisition set-up, etc., and various features designed to enhance image quality.
	The Xeleris 4.0 is a modification of its predicate device Xeleris 3.1 (K130884) by introducing the following additional clinical applications:
	1. **Q.Lung** - Q.Lung application provides processing, quantification, and multidimensional review for pulmonary scintigraphy for display and quantification of global and regional ventilation (V) and perfusion (P) on SPECT and SPECT/CT studies.
	2. **Q.Brain** - Q.Brain application features automated analysis through quantification of tracer uptake and comparison with the corresponding tracer uptake in control subjects. The resulting quantification is presented using volume of interests, voxel-based and 3D stereotactic surface projection maps of the brain.
	Q.Brain image analysis standardizes individual brain shapes into a standard atlas shape while preserving the functional information measured by SPECT and PET imaging.
	SPECT/PET co-registration to MR and fusion display capabilities allows functional findings to be related to anatomy and offers visualization of structural abnormalities.
	3. **Alcyone CFR** – Alcyone CFR application allows for the quantification of coronary vascular function by deriving the Myocardial Blood Flow (MBF) and Coronary Flow Reserve (CFR). These indices may add information to physicians using Myocardial Perfusion Imaging for the diagnosis of Coronary Artery Disease (CAD).

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

	Q.Brain 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, when used with radiopharmaceuticals approved by the regulatory authority in the country of use, 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).
Technology:	The Xeleris 4.0 Processing and Review Software employs the same fundamental scientific technology as that of its predicate device. The software was developed, verified, and validated under GE Healthcare's QMS including software development lifecycle.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The Xeleris 4.0 and its applications have been successfully tested to verify conformance to standards (DICOM Standard NEMA PS3.1 - 3.18; IEC62304). The modifications from the predicate Xeleris 3.1 system were completed in accordance with GE's quality management system and design controls per

	21CFR 820 and ISO 13485. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or identify any new risks. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level • Integration testing • Performance testing • Safety testing • Simulated use testing In addition to the testing successfully completed as required by GE Healthcare's quality system, additional engineering testing was performed to provide the requisite data to substantiate performance claims, revised indications, safety and efficacy, and ultimately substantial equivalence. This testing included: – Demonstration of clinical outputs, workflow and tools. – Scientific measurements for substantiation of technical claims. – Bench measurements on representative clinical datasets for substantiation of clinical performance. Summary of Clinical Tests: The subject of this premarket submission, XELERIS 4.0, did not require clinical studies to support substantial equivalence. However, bench measurements on representative clinical datasets were used to demonstrate the outputs of the software applications, and to substantiate their clinical performance.
Conclusion:	Development and testing of the new features included use of clinically acquired data-sets to ensure the intended clinical outputs were achieved. Verification including hazard mitigation has been performed with results demonstrating the Xeleris 4.0 Processing and Review Workstation software met

	its design inputs and clinical performance requirements. No new hazards were introduced and all existing hazards residual risks remain ALARP.
	The system and its development process comply with International standards.
	The Xeleris 4.0 Processing and Review Workstation Software is developed under the same design controls processes and software development life cycle, as other GE healthcare software post-processing system as the predicate device. Based in the established verification testing GE has determined that Xeleris 4.0 is of comparable type and substantially equivalent to the currently marketed workstation software and to its predicate device described in Xeleris 3.1 (K130884).
	Based on the conformance to standards, development under our quality system, and the extensive engineering testing provided, GE Healthcare believes that the Xeleris 4.0 Processing and Review Workstation is as safe and effective, and performs in a substantially equivalent manner to the predicate device.