

K130884
Page 1 of 6



GE Healthcare
510(k) Premarket Notification Submission

APR 12 2013

Section 5: 510(k) Summary

Xeleris 3.1 Processing and Review Workstation

Throughout of this document the Xeleris 3.1 Processing and Review Workstation is mention also in the relevant documents as project names: Xeleris Skyline, Skyline or Xeleris 3.1. All names are equivalent.

K130884
Page 2 of 6



GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	March 21 2013
Submitter:	GE Healthcare, GE Medical Systems Israel, Functional Imaging 4 Hayozma St TIRAT HACARMEL, 30200, ISRAEL
Primary Contact Person:	Eli Werner Regulatory Affairs Leader GE Healthcare, GE Medical Systems Israel, Functional Imaging +972-4-8563666 +972-4-8577664
Secondary Contact Person:	John Jaeckle Chief Regulatory Affairs Strategist GE Healthcare 262-424-9547
Device Trade Name:	Xeleris 3.1 Processing and Review Workstation
Common/Usual Name:	Nuclear Medicine Workstation
Classification Names: Product Code:	System, Image Processing, Radiological Class II ;21CFR 892.2050 LLZ
Predicate Device(s):	K093982- Xeleris 3 Processing and Review workstation K021656- HERMES HDAQ Acquisition Station and HERMES Workstation, Ver. 3.4 K123528- Scenium 3.0
Device Description:	The Xeleris 3.1 is a Nuclear Medicine Workstation system intended for general nuclear medicine processing & review procedures for detection of radioisotope tracer uptake in the patient body, using a variety of processing modes supported



GE Healthcare
510(k) Premarket Notification Submission

	<p>by various clinical applications types and various features designed to enhance image quality. The components of the Xeleris 3.1 NM Workstation system are: operation console, monitor and peripherals.</p> <p>The Xeleris 3.1 is a modification of its predicate device Xeleris 3 while providing enhanced workflow to existing operations and enabling broader access to Xeleris applications in supporting PACS and GE AW Server and in offline client server configuration. Xeleris 3.1 also enables the use of normal data base comparison together with the quantification analysis of ¹²³I-ioflupane brain NM images. Similar functionality for NM/PET brain image analysis also resides in the predicate devices K021656 and K123528.</p>
<p>Intended Use:</p>	<p>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.</p> <p>The system operates in a variety of configurations. The hardware components may include computer workstations, communications devices, video monitors, data storage and hardcopy devices.</p> <p>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.</p>
<p>Indication of Use</p>	<p>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 NM 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.</p> <p>The system can run on dedicated workstation or in a server-client configuration.</p> <p>The NM or PET data can be coupled with registered</p>

K130884
Page 4 of 6



GE Healthcare
510(k) Premarket Notification Submission

	<p>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.</p> <p>DaTQUANT optional application enables visual evaluation and quantification of ¹²³I-ioflupane (DaTscan™) images. DaTQUANT Normal Database option enables quantification relative to normal population databases of ¹²³I-ioflupane (DaTscan™) images.</p> <p>These applications may assist in detection of loss of functional dopaminergic neuron terminals in the striatum, which is correlated with Parkinson disease.</p>
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GE Healthcare
510(k) Premarket Notification Submission

Technology:	The Xeleris 3.1 Processing and Review Workstation employs the same fundamental scientific technology as its predicate devices Xeleris 3.
Determination of Substantial Equivalence:	<p><u>Summary of Non-Clinical Tests:</u></p> <p>[The Xeleris 3.1 and its applications have been successfully tested to comply with voluntary standards (DICOM Standard NEMA PS3.1 - 3.18; IEC60601-1-4; IEC62304) as detailed in Section 9, of this premarket submission. The modifications from the predicate Xeleris 3 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:</p> <ul style="list-style-type: none">• Risk Analysis• Requirements Reviews• Design Reviews• Testing on unit level (Module verification)• Integration testing (System verification)• Performance testing (Verification)• Safety testing (Verification)• Simulated use testing (Validation) <p>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 substantiate performance claims, revised indications, safety and efficacy, and ultimately substantial equivalence.</p> <p>This testing included:</p> <ul style="list-style-type: none">- Demonstration of workflow and tool improvements- Testing of Advanced Connectivity capabilities- Testing of the Volumetrix MI enhancements related to attenuation correction.- Testing the accuracy of using the DaTQUANT application by comparing DaTQUANT analysis results to manual analysis results. The data that was used for comparison was taken from brain phantoms injected symmetrically and asymmetrically, thus simulating normal and abnormal uptakes in the left and right striatum. Different contrast levels

K.130884
Page 6 of 6



GE Healthcare
510(k) Premarket Notification Submission

	<p>were used to simulate different signal to noise ratio levels. DaTQUANT results were found to be as accurate as manual results.</p> <p>- Clinical scenario testing performed on phantoms simulating clinical applications and situations.</p> <p><u>Summary of Clinical Tests:</u></p> <p>The subject of this premarket submission, XELERIS 3.1, did not require clinical studies to support substantial equivalence. However, clinical scenario testing was performed on the bench.</p>
<p>Conclusion:</p>	<p>Based on the conformance to standards, development under our quality system, and the extensive engineering testing provided, GE Healthcare believes that the Xeleris 3.1 Processing and Review Workstation is as safe and effective, and performs in a substantially equivalent manner to the predicate devices. The device and the predicate devices are image post processing workstations devices and provide similar features of visualization and quantitative analysis.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

GE Healthcare, GE Medical System
% Ned Devine
Sr. Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062

April 12, 2013

Re: K130884

Trade/Device Name: Xelaris 3.1 Processing and Review Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 28, 2013
Received: March 29, 2013

Dear Mr. Devine:

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. 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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris". The signature is stylized and includes a large, bold "J" and "M".

for

Janine M. Morris
Director
Division Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

GE Healthcare
510(k) Premarket Notification Submission



510(k) Number (if known): K130884

Device Name: Xeleris 3.1 Processing and Review Workstation

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 NM 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 ¹²³I-ioflupane (DaTscan™) images. DaTQUANT Normal Database option enables quantification relative to normal population databases of ¹²³I-ioflupane (DaTscan™) images.

These applications may assist in detection of loss of functional dopaminergic neuron terminals in the striatum, which is correlated with Parkinson disease.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Sub part D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) K130884