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 (Image Diagnost International)
% Mr. Mounir Zaouali
Regulatory Affairs Leader
Oskar-Schlemmer-Str. 11
Munich D-80807
GERMANY

August 1, 2016

Re: K160937
Trade/Device Name: SenoIris
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 23, 2016
Received: June 27, 2016

Dear Mr. Zaouali:

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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160937

Device Name
SenoIris

Indications for Use *(Describe)*

SenoIris is designed for diagnostic and non-diagnostic review in diagnostic and screening breast imaging environments through flexible and interactive manipulation of multi-modality, multi-vendor softcopy images.

It provides image review, manipulation, analysis, Post-Processing and printing capabilities for FFDM, DBT, and CESM images. The software also supports the display of CAD, breast density assessments and other breast imaging data from various modalities.

Image routing and compression, as well as centralized workflow steering, including double blind reading and integrated in-image reporting, are part of the solution to support the women's healthcare professionals to enrich existing workflows for breast imaging needs.

Various specific and general interfaces exist to synchronize to other external software on the front- and back-end side. The software also provides functions to directly import data from and export them to mobile storage media or onto the local operating system.

Contraindications
Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless cleared for use in digital mammography.
Review monitors used for primary diagnostic interpretation of mammographic images must be cleared for use in digital mammography.
All images sent to or imported in the SenoIris must fulfill the regulatory requirements. Image quality must conform with applicable quality guidelines.
For Diagnose Mode, all modalities must be certified for soft-copy reading

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

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

Date:	April 1, 2016
Submitter:	GE Healthcare (Image Diagnost International) Oskar-Schlemmer-Str. 11; 80807 München, Germany
Primary Contact Person:	Mounir Zaouali, Regulatory Affairs Leader GE Healthcare, 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 45 39 Fax : + 33 1 30 70 41 40 Email : Mounir.Zaouali@ge.com
Secondary Contact Person:	Diane Uriell Director of Regulatory Affairs, XR and Women's Health GE Healthcare, Atlanta Phone +1 262 290 8212 Email:Diane.Uriell@ge.com .
Device Trade Name:	SenoIris
Common/Usual Name:	Medical imaging software
Classification Names:	Picture archiving and communication system Class II CFR 892.2050 System, Image Processing, Radiological,
Product Code:	LLZ
Predicate Device(s):	MammoWorkstation (K143361)
Device Description:	The SenoIris is a medical image review workstation software for diagnostic and screening mammography. SenoIris has the capability to review Digital Breast Tomosynthesis (DBT) images that are compatible with Breast Tomosynthesis Image Storage. It is a software product

Intended Use:	SenoIris is designed for diagnostic and non- diagnostic review in diagnostic and screening breast imaging environments through flexible and interactive manipulation of multi-modality, multi-vendor softcopy images. It provides image review, manipulation, analysis, Post-Processing and printing capabilities for FFDM, DBT, and CESM images. The software also supports the display of CAD, breast density assessments and other breast imaging data from various modalities. Image routing and compression, as well as centralized workflow steering, including double blind reading and integrated in-image reporting, are part of the solution to support the women's healthcare professionals to enrich existing workflows for breast imaging needs. Various specific and general interfaces exist to synchronize to other external software on the front- and back-end side. The software also provides functions to directly import data from and export them to mobile storage media or onto the local operating system. Contraindications Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless cleared for use in digital mammography. Review monitors used for primary diagnostic interpretation of mammographic images must be cleared for use in digital mammography. All images sent to or imported in the SenoIris must fulfill the regulatory requirements. Image quality must conform with applicable quality guidelines. For Diagnose Mode, all modalities must be certified for soft-copy reading
Technology:	SenoIris is a software product. It is designed to run on a standard workstation with a minimum of three monitors, one control monitor and high-resolution monitor (s) that are cleared for mammography review. It runs on Windows Operating System.
Comparison Of Technological	The following is an overview of the differences between the proposed SenoIris and the predicate MammoWorkstation. Refer

Characteristics With The Predicate Device:	to the Comparison Matrix in Section 12.1 for additional information regarding the changes. <u>SenoIris Configurations</u> As with the predicate device, SenoIris has 3 configurations or modes, The primary difference between the predicate device is that the naming convention and combining of modes into one mode to yield the Connect Mode. 1. The Diagnose Mode is designed to assist radiologists in conducting primary diagnostic interpretation for diagnostic and screening mammography through flexible and interactive manipulation of multimodality softcopy images. This mode has the same functionalities as the currently marketed MammoWorkstation 2. The Review Mode has been designed as the technologist's workplace for the management of clinical data and image display. The Review Mode provides easy access to prior images and reports. . This mode has the same functionalities as the currently marketed MammoDocumentationStation. 3. The Connect Mode enables the SenoIris to send DICOM documents to external systems by telemammography. Furthermore it provides Central User Management, which allows organizing complex, multi-site processes like user-related worklists and automated double reading, particularly for screening. This mode combines the functionalities of the currently marketed Collaboration Server and DicomShuttle. <u>DBT Review – 2D Synthesized Image</u> SenoIris was designed to provide several additional tools for the review of DBT images and mainly to the synthetized 2D image that is called "V-Preview". Modifications include image quality improvement, V-Preview Navigate and V-Preview Inspect. During GE DBT acquisition, 9 projections are performed by angulating the X-rays tube around the central projection (when the main X-ray beam is perpendicular to the detector). The V-Preview image is reconstructed from this central projection by incorporating other information from the other projections. V-Preview is an additional image for navigation use only and does not replace FFDM image.

	Image Quality Improvement SenoIris improves the image quality of V-Preview image by the implementation of a modified generation algorithm by lowering the artefacts and the noise of the image. V-Preview Navigate (with V-Preview Inspect V-Preview Bookmark) SenoIris adds V-Preview Navigate that uses a cross reference mechanism between every point of the V-Preview image to the associated DBT planes or slabs and position within those planes or slabs. So when the user indicates a location in a V-Preview image in one display monitor by clicking on it, the DBT plane or slab containing this structure will be directly displayed in the other second display monitor. . When combined with V-Preview Inspect, the corresponding portion of slab or plane will be displayed in a pop-up small window on the V-Preview image itself. Also, when the V-Preview Bookmark feature is enabled, for every annotations made on any DBT slab or plane a navigation pointer will show on the corresponding area of the V-Preview image. Cybersecurity; The security of SenoIris is also improved from the predicate to be aligned to the recent FDA cybersecurity requirements enforcement through several guidance's (e.g. FDA Guidance, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014). Usability: Other modifications are related to the improvement of the usability of the software with a redesigned user interface with a simpler look. Certain functions and preferences are bound to the user log-in. The software stores and remembers several settings from the last session of the user, for example the hanging protocols and tools bar position, SenoIris provides several images printing improvement including the option for configuring multiple DICOM printers and several printing preferences.

	Accessories Dedicated keypads are accessories to the SenoIris. The keypads operate like standard keyboard and mouse and emit shortcuts similar to that of the standard keyboard or mouse wheel. There is also some flexibility of the configuration of the buttons of the keypads that can be done by the end user and described within the operator manual.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The SenoIris and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) Summary of Clinical Tests: A clinical reader study has been performed and has shown that the image quality of V-Preview of SenoIris is either better or equivalent to the image quality of V-Preview of the predicate device MammoWorkstation.
Conclusion:	GE Healthcare considers the SenoIris to be as safe, as effective, and performance is substantially equivalent to the predicate device.