GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

May 4, 2018

Re: K180641
Trade/Device Name: Invenia ABUS Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 8, 2018
Received: March 12, 2018

Dear Bryan Behn:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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)*

K180641

Device Name
Invenia ABUS Viewer

Indications for Use *(Describe)*

Image Display of Automated Breast Ultrasound (ABUS), as well as other multi-modality DICOM medical images for diagnostic and non-diagnostic review purposes. The device will be used by trained healthcare professionals.

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

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

Date:	March 8, 2018
Submitter:	GE Healthcare 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262)247-5502 F:(414)918-8275
Alternate Contact Person:	Elizabeth Gemmel T: (262)788-3816
Device: Trade Name:	Invenia ABUS Viewer
Common/Usual Name:	Invenia ABUS Viewer
Classification Names:	Class II
Product Code:	Picture archiving and communication system. 21 CFR 892.2050 LLZ
Primary Predicate Device:	K151075 BR-ABVS Viewer 1.0
Reference Predicate Device(s):	K150420 Centricity Universal Viewer
Device Description:	The Invenia ABUS Viewer is intended for the image display of breast ultrasound images. The Invenia ABUS Viewer can received, transmit, and display medical images and associated patient medical information from the Invenia ABUS Scan Station as well as from other ultrasound or image acquisition devices.
Indications for Use:	Image display of Automated Breast Ultrasound (ABUS), as well as other multi-modality DICOM medical images for diagnostic and non-diagnostic review purposes. The device will be used by trained healthcare professionals. Invenia ABUS Viewer employs the same fundamental scientific technology as its predicate device(s).

Technology:

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Invenia ABUS Viewer is a new platform substantially equivalent to the predicate devices. The following is an overview of the similarities between the proposed Invenia ABUS Viewer and the predicate BR-ABVS Viewer 1.0 (K151075). The systems are all intended for picture archiving and communication systems.

- The Invenia ABUS Viewer and predicate BR-ABVS Viewer 1.0 software have the same clinical applications.
- Both software systems operate/devices on the same operating platform.
- Invenia ABUS Viewer and predicate have the same image processing techniques.
- The software systems/devices process the same type of images.
- The Invenia ABUS Viewer and predicate BR-ABVS software systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The Invenia and predicate operate with the same main interfaces of connectivity and archiving

The reference predicate, Centricity Universal Viewer, and Invenia ABUS Viewer are also similar in that they display medical images from various sources and utilize DICOM.

Summary of Non-Clinical Tests:

The Invenia ABUS Viewer and its applications comply with voluntary standards:

- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
- IEC 62304, Medical device software – Software life cycle processes

The following quality assurance measures are applied to the development of the system:

- Risk Analysis

- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Invenia ABUS Viewer, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Invenia ABUS Viewer to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).