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
% Ms. Cheryl Bork
Regulatory Affairs Manager
540 W. Northwest Highway
BARRINGTON IL 60010

May 26, 2015

Re: K150420
Trade/Device Name: Centricity Universal Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 13, 2015
Received: April 15, 2015

Dear Ms. Bork:

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K150420

Device Name

Centricity Universal Viewer

Indications for Use *(Describe)*

Centricity Universal Viewer is a device that displays medical images and data from various imaging sources, and from other healthcare information sources. Medical images and data can be displayed, communicated, stored, and processed.

Typical users of this system are authorized healthcare professionals.

Centricity Universal Viewer is intended to assist in the viewing, analysis, diagnostic interpretation, and sharing of images and other information.

Mammography images may only be interpreted using a monitor compliant with requirements of local regulations and must meet other technical specifications reviewed and accepted by the local regulatory agencies.

Contraindications:

Centricity Universal Viewer is contraindicated for the use of lossy compressed mammographic images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

I. SUBMITTER

GE Healthcare
540 West Northwest Highway
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GE Healthcare
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Regulatory Affairs
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Date Prepared: May 21, 2015

II. DEVICE

Name of Device:	Centricity Universal Viewer
Common Name:	Picture Archiving and Communication System
Classification Name:	21 CFR 892.2050, System, Image Processing, Radiological
Regulatory Class:	II
Product Code:	LLZ

III. PREDICATE DEVICE

K123174 - GE Healthcare Centricity PACS-IW with Universal Viewer
This predicate device was subject to ONE design-related recall in Oct-13-2013. However, this performance issue has been reviewed and mitigated. A detailed description can be found in Section 21. Total Product Life Cycle (TPLC).

IV. DEVICE DESCRIPTION

Centricity Universal Viewer is an Internet based medical image display and interpretation software product that is part of a picture archiving and communications system that assists radiologists and cardiologists in their diagnostic workflows. It provides users with capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images (including digital mammograms).

Centricity Universal Viewer provides APIs (Application Program Interfaces) to integrate with third-party medical devices and non-medical devices, which include integration with Tomtec-Arena™ (K132544) for advanced cardiology applications.

Centricity Universal Viewer supports DICOM SOP classes to access and manage medical imaging studies from , Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Nuclear Medicine (NM), Computerized Radiography (CR), Digital mammography (MG), Digital X-ray (DX), Positron Emission Tomography (PET/PT), X-Ray Angiography (XA), Digital Intra-oral X-Ray (IO), Radiofluoroscopic X-ray (RF), Secondary Capture Images (SC), Visible Light (VL) Endoscopic, Microscopic and Photographic Image Storage, Slide Coordinates Microscopic Image Storage, Presentation States (PS), Key Image Notes (KIN), and other DICOM imaging modalities.

Centricity Universal Viewer is not intended for the diagnosis of digital pathology images.

Centricity Universal Viewer is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms and operating systems.

The system does not produce any original medical images. All images located on the Centricity Universal Viewer have been received from DICOM compliant modalities and/or image acquisition systems.

V. INDICATIONS FOR USE

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Centricity Universal Viewer is intended to assist in the viewing, analysis, diagnostic interpretation, and sharing of images and other information.

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Contraindications:
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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Centricity Universal Viewer device employs the same fundamental scientific technology as its predicate device, Centricity PACS-IW with Universal Viewer cleared under K123174, with the following modifications:

- Expanding the capabilities of Centricity Universal Viewer for Cardiology in addition to Radiology applications.
- Modified viewer to present a common unified workspace for radiologists, cardiologists and clinicians to perform the review, manipulation and diagnostic interpretation of images and other information generated by acquisition.
- Hardware specifications minimum specifications were modified as a result of technology advancements and obsolescence issues.

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Centricity Universal Viewer complies with voluntary standards as detailed in this premarket notification submission.

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Usability Analysis
- Testing on unit level (Verification)
- Integration testing (Verification)
- Performance testing (Verification)
- Regression testing (Verification)
- System testing (Verification)
- Simulated use testing (Validation)

The subject of this submission, Centricity Universal Viewer, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

VIII. CONCLUSION

Comparison of the Intended Uses / Indications for Use, the technological characteristics, and performance specifications demonstrate the functional equivalence of the subject device to the predicate device.

Verification and Validation testing results demonstrate that no adverse effects have been introduced by these differences.

The Centricity Universal Viewer device will continue to have an intended use and functionality fitting within the definition of 21 CFR 892.2050, Picture Archiving and Communication Systems, Product Code LLZ.

Information provided in this premarket notification submission supports the Centricity Universal Viewer medical device to be as safe, as effective and substantially equivalent to its predicate device.