May 21, 2021

GE Healthcare
c/o Mr. John Braam
Regulatory Affairs Leader
500 W. Monroe Street
CHICAGO IL 60661-3671

Re: K211312
Trade/Device Name: Universal Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 29, 2021
Received: April 30, 2021

Dear Mr. John Braam:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211312

Device Name
Universal Viewer

Indications for Use *(Describe)*

Universal Viewer is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display and measurement of image data.

Typical users of this system are authorized healthcare professionals.

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.

Lossy compressed mammographic images and digitized film screen images should not be reviewed for primary image interpretations with use of the Universal Viewer.

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
K211312

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

Date:	April 29, 2021
Submitter:	GE Healthcare Establishment Registration Number - 3004526608 500 W. Monroe Street Chicago, IL 60661
Primary Contact Person:	John Braam Regulatory Affairs Leader Tel: 262-347-8240 Email: john.braam@ge.com
Secondary Contact Person:	Elizabeth Mathew Senior Regulatory Affairs Manager Tel: 262-424-7774 Email: Elizabeth.Mathew@ge.com
Device Trade Name:	Universal Viewer
Common/Usual Name:	UV
Proposed Device: Primary Regulation Number: Primary Product Code: Regulatory Class:	Universal Viewer 21 CFR 892.2050 – Medical Image Management and Processing System LLZ Class II
Predicate Device: 510(k) number Regulation Number: Product Code: Regulatory Class: Manufacturer:	Centricity Universal Viewer K182419 21CFR 892.2050 – Picture Archiving and Communications System LLZ Class II GE Healthcare 500 W. Monroe Street, Chicago, IL – 60661 USA

Device Description:

Universal Viewer is an Internet based medical image display and interpretation software product that is part of a medical image management and processing system. It provides users with capabilities relating to the acceptance, transfer, display, and digital processing of medical images.

The Universal Viewer product does not produce any original medical images. All images displayed by Universal Viewer have been received from DICOM compliant modalities and/or image acquisition systems.

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.

Universal Viewer provides image manipulation tools to enable users to view and compare images such as: measurements (linear distances, angles, areas, SUV, etc.), annotations (outline and label regions of interest, label spinal vertebrae), MPR, MIP, and 3D image fusion of CT, PET and registration of CT, PET and MR.

Universal Viewer is designed to be deployed over conventional Transmission Control Protocol/Internet Protocol (TCP/IP) networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms and operating systems.

Universal Viewer provides Application Program Interfaces (APIs) to integrate with third-party medical devices and non-medical devices.

Intended Use:

Universal Viewer is a software application that displays medical image data and associated clinical reports to aid in diagnosis for healthcare professionals. It performs operations relating to the transfer, storage, display, and measurement of image data.

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Typical users of this system are authorized healthcare professionals.

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.

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Technology:

The subject device Universal Viewer employs the same fundamental scientific technology as its predicate device.

Comparison:

The table below summarizes the feature/technological comparison between the predicate device and the proposed device:

Feature	Predicate Device Centricity Universal Viewer (K182419)	Proposed Device Universal Viewer	Discussion of Differences
Backend Integration	Centricity PACS (K110875) and Enterprise Archive	Enterprise Archive	Substantially Equivalent. Simplified Integration with GE Healthcare's Enterprise Archive (EA) for unified short- and long-term storage for the image and non-image data and study management workflow
Image Display and Review	Yes	Yes	Identical
Image Annotations and measurements	Yes	Yes	Identical
General Workflow including, Exam Search Exam Assignments System and Custom Worklists Reporting Workflow	Available in the UV study list and/or Workflow Manager if enabled	Available in Workflow Manager	Substantially Equivalent. Consolidated to one worklist.

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing:

The Universal Viewer device has successfully completed the required design control testing per GE's quality system. Universal Viewer was designed and manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485.

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

- Risk Analysis
- Requirements Reviews

- Design Reviews
- Performance testing (Verification, validation)
- Safety testing (Verification)

The testing and results did not raise new questions of safety and effectiveness from those associated with predicate device and demonstrated that the Universal Viewer device performs substantially equivalent to the predicate device.

The substantial equivalence determination is also based on the software documentation for a MODERATE level of concern device.

Conclusion:

Based on the development under our quality system, and the engineering testing provided, GE Healthcare believes that Universal Viewer is as safe and effective and performs in a substantially equivalent manner to the predicate device Centricity Universal Viewer (K182419).