December 14, 2018

GE Healthcare
Renee Webb
Senior Regulatory Affairs Manager
500 West Monroe Street
CHICAGO, IL 60661

Re: K182419
Trade/Device Name: Centricity Universal Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 20, 2018
Received: September 26, 2018

Dear Renee Webb:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

for
Robert A. 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)*
K182419

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
500 West Monroe
Chicago, IL 60661

Primary Contact Person: Renee Webb
Senior Regulatory Affairs Manager
GE Healthcare
Phone: 847-707-8783

Secondary Contact Person: John Manarik
Regulatory Affairs Manager
GE Healthcare
Phone: 224-532-0907

Date Prepared: December 12, 2018

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

Primary - K150420 (May 2015)- Centricity Universal Viewer by GE Healthcare
Reference - K063628 (December 2006) -Centricity Radiology RA600, Cardiology CA1000 and Digital Hardcopy.

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 ™ [1] 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.

[1] Tomtec-Arena™ K132544 has been FDA cleared and CE Marked.

V. INDICATIONS FOR USE

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.

The Intended Use / Indications for Use statement is identical to the Predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject Centricity Universal Viewer device continues to support the display, storage, analysis and processing of various medical images using similar technology.

The basis for this premarket notification is a modification of the legally marketed Centricity Universal Viewer device to incorporate additional features. These modifications do not change the Intended Use. These changes include enhancements and other updates to support customer feedback and to enhance usability of the software application. These modifications improve on the subject device's ability to assist healthcare professionals in the display, storage, processing, and diagnostic analysis of various medical images similarly to the predicate Centricity Universal Viewer.

The Centricity Universal Viewer architecture and SOUP software and software core algorithms have not changed. The Cath Tools algorithm has not changed. Cath Tools adds functionality that already existed in K063628 onto the Centricity Universal Viewer software technology stack.

The following table contains a comparison of the key changes since the last 510k clearance K150420:

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
Intended Use / Indications For Use	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.	Identical to predicate device	No change
Contraindication	Centricity Universal Viewer is contraindicated for the use of lossy compressed mammographic images.	Identical to predicate device	No change

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
	Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.		
Cath Analysis Tools	Not supported	Supported in the subject device. The following tools are available to help perform an analysis of images received as a result of a catheterization procedure: 1. Stenosis Analysis 2. Left ventricular analysis 3. Catheter calibration • Point to Point Calibration • Calibration extension 4. Distance measurement	Equivalent. Cath Tools modifications do not change the Intended Use. The Cath Tools functionality added is identical to the Cath Tools in GE Healthcare's, Centricity Radiology RA600, Cardiology CA1000 cleared under K063628. Test results for these modifications do not raise different issues of safety or effectiveness. There are no new potential hazards and no changes to existing potential hazards, and no change in the final risk ratings for the device.
Workflow			
Interactive search for studies	Search by: 1. Patient name 2. ID 3. Accession Number 4. Study date 5. Study description 6. Modality 7. Study status 8. Referring Physician 9. Date of Birth 10. Referring Service	Same as predicate, except: - Retrieval of off-line study - Access to confidential patient studies based on privileges - Increase number of studies the	Equivalent. Adding the modifications under interactive search for studies does not impact the device safety and effectiveness.

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
	11. Priority 12. Online status (CPACS only) 13. 0 image studies (CPACS only) 14. Performing physician 15. Location (Enterprise Archive (EA) only for Cardiology)	worklist can display and remove 30 study limit on custom worklists - Support for Technologist study verification workflow and teaching folder - Create, access, save and display key images	
Search from DICOM server	Search for studies located on the external DICOM compliant server. Supported only on IW backend	Same as predicate, except: - search and retrieve prior exams from external DICOM server - save and display DICOM grayscale presentation state object to work with any type of under lying hanging protocol	Equivalent. Adding the modifications under the search from DICOM server does not impact the device safety and effectiveness.
Image Display			
Ability to display information	Ability to display the following: 1. Image 2. Report 3. Patient information 4. Exam information 5. DICOM Header information 6. GSPS 7. RPPS 8. FCE 9. Key Image Notes 10. Exam Notes	Same as predicate, except: - native support of diagnostic interpretation for 2D and DBT mammo images - user, group and system level step protocols - support DICOM metadata in overlay /	Equivalent. These modifications do not change the Intended Use. The device continues to support the display, storage, analysis and processing of various medical images using a similar technology. Test results for these modifications do not raise different issues

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
	11. Modality and VOI LUT 12. Structured Reports	annotation editor - support synchronized ECG curve, ECG scroll and ECG curve height selector - support Dorsal view (Reverse ACR IHE) for mammography	of safety or effectiveness. There are no new potential hazards and no changes to existing potential hazards, and no change in the final risk ratings for the device.
Image Annotations and measurements	1. Line 2. Angle 3. SUV 4. OB Measurements 5. Digital Subtraction Angiography (DSA) 6. Triangulation 7. MIP/MPR 8. Spine Labeling 9. Using "imager pixel spacing" - DICOM field to enable measurements across all CR/DX/US exams. 10. Cardio Thoracic Ratio (CTR) 11. Image Annotations	Same as predicate, except: - Automatically mark images as key when image is annotated - Use "imager pixel spacing" DICOM field to enable measurements across CR/DX/US exams	Equivalent. Adding the modifications for image annotations and measurements does not impact the device safety and effectiveness. These enhancements provide information already available to be used in the same way as the predicate, for the same purpose and by the same users.
Customized Hanging Protocols	Smart Reading Protocols -Regular Hanging protocols to launch multiple MIP/MPRs	Same as predicate, except: - multi-modality and multi-vendor hanging protocol - dedicated toolbar for mammography features - smart reading protocols learn user's preferences for MRI multiphasic studies	Equivalent. Adding the modifications for customized hanging protocols does not impact the device safety and effectiveness. These enhancements provide information to be used in the same way as the predicate, for the same purpose and by the same users.
Maximum Intensity	Maximum Intensity Projection (MIP) MIP with	Same as predicate, except:	Equivalent. These modifications do not

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
Projection (MIP) MIP with interactive window-level clipping volume of interest, zoom, pan, and rotate	interactive window-level clipping volume of interest, zoom, pan, and rotate	- Recalculate standard update value on the fly for PET/CT images - Multi-planar reconstruction support multiple oblique reconstruction - Support for non-square pixel image calibration	change the Intended Use. The device continues to support the display, storage, analysis and processing of various medical images using a similar technology. Test results for these modifications do not raise different issues of safety or effectiveness. There are no new potential hazards and no changes to existing potential hazards, and no change in the final risk ratings for the device.
Printing			
Key Images/Print Pages	Created Print Pages from selected Key Images, one-click placement; customized templates; one click-full screen snapshot	Identical to predicate device	No change
Print to Film / Paper	Print collage of images to printer	Identical to predicate device	No change
Connectivity, Interfaces & Interoperability			
Integration	Integration COM service	Identical to predicate device	No change
Interfaces	Generic interface to integrate outbound with third party applications and internal GEHC applications that meet the interface requirements.	Same as predicate, except: - Update to API connectivity to launch newer versions of 3rd party software	Equivalent. Adding modifications for the interfaces does not impact the device safety and effectiveness. There are no new potential

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
		applications such as GE Healthcare's EchoPAC and Advantage Workstation applications	hazards and no changes to existing potential hazards, and no change in the final risk ratings for the device.
External system launch	The viewer can be launched via a 3rd party application using the following methods: 1. url launch 2. IVAPI 3. Inbound API	Same as predicate, except: - Updates in interfaces with 3rd party software applications - URL launch using SUID when study associated with multiple orders	Equivalent. Adding modifications under external system launch does not impact the device safety and effectiveness. These enhancements provide information to be used in the same way as the predicate, for the same purpose and by the same users.
Administrative			
Interactive query	In console, supporting wildcards	Identical to predicate device	No change
Setup	Wizard and silent	Identical to predicate device	No change
On-line help	Yes	Identical to predicate device	No change
User Interface and User Manual Languages	1. English, 2. German, 3. Japanese, 4. French, 5. Simplified Chinese 6. Italian, 7. Polish, 8. Spanish 9. Turkish, 10. Brazilian Portuguese, 11. Dutch, 12. Swedish, 13. Russian 14. Korean, 15. Finnish, 16. Danish, 17. Norwegian, 18. Traditional Chinese 19. Portuguese, 20. Greek, 21. Hungarian	Identical to predicate device	No change

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
Administrative rights assignment	Per user/group	Identical to predicate device	No change
Automatic notification messages	By email. HL7	Same as predicate, except: - auto refresh and notification when new images arrive - merge two studies into one - audit log to track export of images	Equivalent. Adding modifications under automatic notification messages does not impact the device safety and effectiveness. These enhancements provide information to be used in the same way as the predicate, for the same purpose and by the same users.
System logging	Combined system log	Identical to predicate device	No change
Compression	Wavelet compression 1. JPEG2000 lossless 2. JPEG2000 lossy Non-wavelet compression 1. JPEG lossless 2. JPEG lossy JPEG2000 lossless for images received uncompressed	Identical to predicate device	No change
Minimal System Requirements			
Offering	1. Turnkey solution (GEHC IT provides both the software and hardware required to function as a complete system) 2. Software only solution (GEHC IT provides and deploys the Software).	Identical to predicate device	No change
ESXi	VMware vSphere ESXi	Identical to predicate device	No change

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
Workstation Features			
Operating System for Diagnostic Workstation	Microsoft™ Windows 7 - 64 bit Microsoft™ Windows 8.1 - 64 bit	Same as predicate, except: - adding support for Windows 10 operating system 32 or 64 bit with Internet Explorer 11	Equivalent. Adding support for Windows 10 operating system 32 or 64 bit with Internet Explorer 11 does not impact the device safety and effectiveness.
Minimum Hardware requirement for Diagnostic Workstation	2 Quad-core processor of 2.0 GHz or more 8GB RAM minimum 146GB drive in Raid 0 configuration DVD-RW Optical drive One 1GB NIC 10/100/1000 Mb Ethernet network 4 Mbps and faster TCP-IP network	Identical to predicate device	No change
Security			
User Authentication using a 3rd Party Authentication Server	Active Directory	Same as predicate, except: - Provides common authentication - security hardening and cybersecurity improvements	Equivalent. Adding common authentication support and security hardening does not impact the device safety and effectiveness.
Enterprise Imaging			
DICOM Protocol	1. Supports DICOM SOP classes 2. Receive images - DICOM storage SCP 3. Support DICOM 3.0 input 4. gray scale	Same as predicate, except: - support additional color (YBR) interpretations with US images - support saving	Equivalent. Adding modifications under DICOM protocol does not impact the device safety and effectiveness. These enhancements

Feature	Predicate Device Centricity Universal Viewer (K150420)	Subject Device Centricity Universal Viewer with Cath Tools	Discussion of Differences
	presentation states	image calibration information in Presentation State	provide information to be used in the same way as the predicate, for the same purpose and by the same users.
(XED) Cross Enterprise Display	Provides the ability to view patient information across multiple enterprise sites based on matching patient ID numbers.	Same as predicate, except: - New API to access patient history in FHIR format and from different sources - Enhance ability to group studies anatomically - matching patient studies from remote sites with the same patient	Equivalent. Adding modifications under cross enterprise display does not impact the device safety and effectiveness. These enhancements allow patient history to be used in the same way as the predicate, for the same purpose and by the same users.
User Environment			
Designed to be utilized inside and outside of radiology	Designed to be utilized inside and outside of radiology and cardiology	Identical to predicate device	No change

VII. PERFORMANCE DATA

Summary of Non-Clinical Tests

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

The Centricity Universal Viewer with the proposed modifications has been verified against design requirements and validated against defined user needs and intended uses, in accordance with the voluntary standards as detailed in this premarket notification submission. The same Cath Tools features were previously cleared in the premarket notification K063628.

The performance characteristics of the Centricity Universal Viewer has been verified against design requirements and validated against defined user needs and intended uses as follows:

- Validation of user needs and intended uses was performed using the recommended hardware platform
- System verification testing of system level requirements was performed using the recommended hardware platform
- Regression testing included in verification testing
- Integration and interoperability verification testing of software functional requirements
- Unit testing of Product Design Detail (PDD) statements
- Product usability formative and summative testing
- Cybersecurity analysis

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

A comparison of the Intended Use / 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 demonstrate that the Centricity Universal Viewer continues to provide a reasonable assurance of safety and effectiveness with respect to the intended use of each feature. Regression testing confirmed that changes did not affect previously cleared features of the Centricity Universal Viewer.

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.