

## 510k Summary

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

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| Date: | Original filing on June 24th, 2013<br>Supplemental Information on September 3rd, 2013 |
| Submitter: | GE Healthcare<br>540 West Northwest Highway<br>Barrington, IL 60010 |
| Primary Contact Person: | Nicole Landreville<br>Regulatory Affairs Manager<br>GE Healthcare<br>Phone: 289-208-2365<br>Fax: 847-277-4506 |
| Secondary Contact Person: | Cheryl Bork<br>Regulatory Affairs Manager<br>GE Healthcare<br>Phone: 847-277-6038<br>Fax: 847-277-5240 |
| Device Trade Name: | Centricity Universal Viewer Zero Footprint client |
| Common/Usual Name: | Picture Archiving and Communication System |
| Classification Names: | 21 CFR 892.2050, System, Image Processing, Radiological |
| Product Code: | LLZ |
| Predicate Device: | K123174 - GE Healthcare Centricity PACS-IW with Universal Viewer |

SEP 17 2013

Device Description: Centricity Universal Viewer Zero Footprint client (ZFP) is a medical software system that is intended for multiple users to remotely access the images stored in a compatible Picture Archiving and Communication System, from compatible computers or workstations on a network, for the purpose of review, diagnostic interpretation and post-diagnostic review of medical images and reports.

ZFP is a viewer that does not produce any original medical images nor does it alter any images or medical data. Specifically, ZFP is an HTML 5 based viewer which runs within a compatible web browser and supports secure transmission of data.

ZFP operates within an operating environment that meets defined minimum specifications (see Section 11.1 for Hardware Description). Both the client and server software of ZFP are only for use with off the shelf hardware technology that meets defined minimum specifications.

ZFP can access data created in multiple systems when stored in Centricity™ Clinical Archive solution and Centricity PACS. Additionally, ZFP can access data from any DICOM compliant archive using Enterprise Archive for query retrieve and data moves.

Authorized users can use the diagnostic quality images for diagnostic purposes. These Authorized users include but are not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Intended Use:

Centricity Universal Viewer Zero Footprint client is a device that displays medical images, data from various imaging sources, and other healthcare information sources. Medical images and data can be viewed, communicated, processed and displayed within a computer network or on a workstation. The device may be used to provide images for diagnostic purposes by trained professionals.

Typical users of this system are authorized individuals and trained healthcare professionals who view medical images and data.

Mammographic 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 Zero Footprint client 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.

Discussion regarding the modifications to the Intended Use / Indications for Use

The Intended Use / Indications for Use statement was modified from the Predicate device to clarify the following:

- The Subject Device, ZFP, is designed to display medical images, data from various imaging sources and other healthcare information sources while Centricity PACS-IW with Universal Viewer Web Client v.5.0 is designed for a broader set of functions, which include the storage of images and data, the communication of images and data as well as the processing of images and data.
- To clarify the conditions regarding appropriate diagnostic usage. The verbiage was clarified to explicitly describe that for mammographic images the user needs to use monitors compliant with requirements of local regulations as regulated by the local regulatory agencies (such as FDA). The use of lossy compressed images is now stated in a separate contraindications statement to raise the importance of using the appropriate type of mammographic images to support primary image interpretations.

Discussion regarding the modifications to the Intended Use / Indications for Use (con't)

The ZFP's Intended Use / Indications for Use statement contains a subset of the predicate device's Intended Use / Indications for Use. These modifications do not impact the equivalence to the predicate in terms of intended use. Specific differences between the Predicate and the Subject device are included in the Section 12: Substantial Equivalence.

Technology:

Centricity Universal Viewer Zero Footprint client displays medical images and other information from various data sources. The information can be processed and displayed across computer networks at dispersed locations.

ZFP is a software-only device that runs on commercially available off-the-shelf computer hardware platforms.

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

1. ZFP now provides compatibility with Centricity PACS.

2. New ZFP enhancements provide support for the following:
   - Side-by-side Comparison
   - Patient level inbound URL launch
   - Secure Inbound URL token authentication
   - Internet Explorer 7 & 8 support via Google Chrome Frame
   - Internet Explorer 9 & 10 support
   - Safari, Firefox support
   - Localizable - multiple date format
   - UTF-16 Character Encoding Scheme
   - Up to 4 multi-frame cine running in parallel
   - Zoom and pan during cine

3. ZFP may now be accessed from an iPad with internet access. When accessed from the Apple® iPad®, ZFP can only be used in review only mode and is not meant for primary diagnosis. Other mobile devices, smartphones and tablets have not been validated.

Determination of Substantial Equivalence:

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". Universal Viewer ZFP client complies with voluntary standards as detailed in this premarket notification submission (Refer to Section 9 - Declaration of Conformity and Summary Reports).

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)
- Regression testing (Verification)
- System testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket notification submission, Centricity Universal Viewer Zero Footprint client, did not require clinical studies to support substantial equivalence.

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 Zero Footprint client 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 Zero Footprint client medical device to be as safe, as effective and substantially equivalent to its predicate device.

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

September 17, 2013

GE Healthcare
% Ms Nicole Landreville
Regulatory Intelligence Manager
540 West Northwest Highway
BARRINGTON IL 60010

Re: K131977
Trade/Device Name: Centricity Universal Viewer Zero Footprint client
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 4, 2013
Received: September 6, 2013

Dear Ms. Landreville:

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.

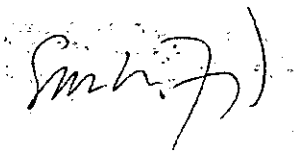
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131977

Device Name: Centricity Universal Viewer Zero Footprint client

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K131977_____