



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Virtual Radiologic Corporation
% Ms. Melinda Sewell
Quality and Regulatory Compliance Manager
11995 Singletree Lane, Suite 500
EDEN PRAIRIE MN 55344

October 25, 2016

Re: K162145

Trade/Device Name: vRad PACS with Mammography
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 7, 2016
Received: October 11, 2016

Dear Ms. Sewell:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K162145

Device Name

vRad PACS with Mammography

Indications for Use (Describe)

The vRad PACS with Mammography software is used with general purpose computing hardware which meets or exceeds minimum specifications. vRad PACS with Mammography is intended to receive, transmit, store, and display images for clinical purposes and is comprised of three components: Viewer, Storage, and Cache. The vRad PACS Viewer component is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with vRad PACS Storage component. The vRad PACS Viewer is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The vRad PACS Viewer can process medical images from DICOM modalities such as X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM-compliant modalities. The vRad Storage component is intended to handle the DICOM protocol and store images as DICOM files to a location where they can be read by vRad PACS Cache and transmitted to radiologists' workstations for viewing by the vRad PACS Viewer.

vRad PACS with Mammography may be used for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM "For Presentation" format and displayed on a monitor that meets technical specifications reviewed and cleared by FDA.

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 for vRad PACS with Mammography

Applicant:

Virtual Radiologic Corporation
11995 Singletree Lane, Suite 500
Eden Prairie, MN 55344

Establishment Registration

Number: 3007795813

Telephone: 952.595.1100

Fax: 952.942.3361

Company Contact: Melinda Sewell, Quality and Regulatory
Compliance Manager

Date Prepared: October 7, 2016

Device Name and Classification:

Proprietary Name: vRad PACS with Mammography
Device Common Name: Picture Archiving and Communications System
(PACS)
Classification Name: System, Image Processing, Radiological
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Device Classification: Class II
Review Panel: Radiology

Predicate Device:

FujiFilm Medical Systems, Synapse Workstation Software Version 3.3.0,
K112439

Device Description:

vRad PACS with Mammography is a device which consists solely of software that allows electronic transmission of radiological patient images from one location to another. The device is capable of accepting, storing, digitally

processing, and displaying medical images for the purposes of providing digital diagnostic image interpretation services by trained radiologists on PC workstations. The software provides functions for performing operations related to manipulation, enhancement, compression, and quantification of medical images.

vRad PACS with Mammography is a modified version of vRad PACS (K090649) that will now allow display of presentation-quality digital mammography images.

Indications for Use:

The vRad PACS with Mammography software is used with general-purpose computing hardware which meets or exceeds minimum specifications. vRad PACS with Mammography is intended to receive, transmit, store, and display images for clinical purposes and is comprised of three components: Viewer, Storage, and Cache. The vRad PACS Viewer component is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with vRad PACS Storage component. The vRad PACS Viewer is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The vRad PACS Viewer can process medical images from DICOM modalities such as X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM-compliant modalities. The vRad Storage component is intended to handle the DICOM protocol and store images as DICOM files to a location where they can be read by vRad PACS Cache and transmitted to radiologists' workstations for viewing by the vRad PACS Viewer.

vRad PACS with Mammography may be used for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM "For Presentation" format and displayed on a monitor that meets technical specifications reviewed and cleared by FDA.

Substantial Equivalence Comparison:

Virtual Radiologic believes vRad PACS with Mammography is substantially equivalent to Synapse Workstation.

Functional Comparison:

Characteristic	vRad PACS with Mammography	Synapse Workstation (K112439)
Indications for Use	The vRad PACS with Mammography software is intended for use with general purpose	FujiFilm Synapse Workstation Software is intended for installation on an off-the-shelf PC

Characteristic	vRad PACS with Mammography	Synapse Workstation (K112439)
	<p>computing hardware which meets or exceeds minimum specifications. vRad PACS with Mammography is intended to receive, transmit, store and display images for clinical purposes and is comprised of three components: Viewer, Storage, and Cache. The vRad PACS Viewer component is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with the vRad PACS Storage component. The vRad PACS Viewer is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The vRad PACS Viewer can process medical images from DICOM modalities such as X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine, and images from other DICOM-compliant modalities. The vRad Storage component is intended to handle the DICOM protocol and store images as DICOM files to a location where they can be read by vRad PACS Cache and transmitted to radiologists' workstations for viewing by the vRad PACS Viewer.</p>	<p>meeting or exceeding minimum specifications and networked with Fuji Synapse PACS. The Fuji Synapse Workstation is intended to serve as the primary user interface for the processing of medical images for presentation on displays appropriate to the medical task being performed. The Synapse Workstation can process medical images from the following modality types: plane X-ray radiography, X-ray computed tomography, magnetic resonance imaging, ultrasound, nuclear medicine and images from other DICOM compliant modalities.</p> <p>The Synapse Workstation may be used to process DICOM MG "For Processing" images and also for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM For Presentation format and displayed on FDA cleared, DICOM compatible displays for mammography.</p>

Characteristic	vRad PACS with Mammography	Synapse Workstation (K112439)
	vRad PACS with Mammography may be used for the display, manipulation, and interpretation of lossless compressed or non-compressed mammography images that have been received in the DICOM" For Presentation" format and displayed on an FDA-approved monitor that meets technical specifications reviewed and accepted by FDA.	
Display of Digital Mammography Images	Yes	Yes
On-demand access to database and images	Yes	Yes
Viewing study lists	Yes	Yes
Decompression for compressed images before display	Yes	Yes
Display images	Yes	Yes
Viewing reports	Yes	Yes
Hanging protocol	Yes	Yes
Spine labeling	Yes	Yes
Reference line display	Yes	Yes
Key images identification	Yes	Yes
Link multiple series	Yes	Yes
Measurement tools	Yes	Yes
Annotation tools	Yes	Yes
Standard image manipulation tools (Window width/level, zoom, pan, etc)	Yes	Yes

Characteristic	vRad PACS with Mammography	Synapse Workstation (K112439)
FCR IPSS for Fuji-CR images	No (proprietary to Fujifilm)	Yes
CT IPSS for CT images	No (proprietary to Fujifilm)	Yes

Technical Comparison:

Characteristic	vRad PACS with Mammography	Synapse Workstation (K112439)
Product availability	Software only	Software only
Operating Systems	Windows 7	Windows 2000/XP
Web Browser	Internet Explorer	Internet Explorer
Image and Data Processing	Client Side	Client Side
Technology Platform (Client)	Windows .Net	Windows Active-X
Technology Platform (Server)	Windows Server	Windows Server
Programming Languages (Client)	C++, C# .Net	C++, Active-X

Safety Information

vRad PACS with Mammography introduces no new safety or efficacy issues other than those already identified with the cleared vRad PACS (K090649). The results of the hazard analysis combined with the appropriate mitigations taken indicate that the device is of moderate concern, as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The vRad PACS with Mammography labeling contains instructions for use and necessary cautions, warnings, and notes to provide the safe and effective use of the device.

Testing Information

vRad PACS with Mammography tested successfully with reference to its product requirements, as well as design verification and validation document and traceability matrix document. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the

vRad PACS with Mammography software, which is found to be as safe and effective as the predicate device.

Testing involved system-level functionality test, component testing, verification testing, integration testing, usability testing, labeling testing, as well as the testing for risk mitigations associated with the risk management process.

Pass/fail criteria were based on the requirements and intended use of the product. Test result results showed that all tests successfully passed.

Performance Standards:

The subject device is in compliance with the following standards:

- NEMA PS 3.1 – 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
- IEC 62304 Ed. 1.1 (2015) Medical Device Software - Software Life Cycle Processes
- ISO 14971 2nd Ed. (2007) Medical Devices - Application Of Risk Management To Medical Devices
- ISO 16142-1, 1st Ed. (2016) Medical Devices - Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards.

This 510(k) submission was prepared in consideration of the following guidance documents:

- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices (2000)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (2014)
- Applying Human Factors and Usability Engineering to Medical Devices (2016)
- Display Accessories for Full-Field Digital Mammography Systems – Premarket Notification (510(k)) Submissions (2008)
- Guidance for Off the Shelf Software Used in Medical Devices (1999)

Conclusion

The predicate device was cleared based on non-clinical supportive information. The comparison of features, technical characteristics, devices hazards, and verification and validation testing demonstrate that the subject device is as safe

and effective as the predicate device currently marketed for the same intended use.

In conclusion, the subject device, vRad PACS with Mammography does not introduce any new significant potential safety risks and is substantially equivalent to the predicate device in terms of performance, safety and effectiveness.