Virtual Radiologic Corporation
% Ellie Reynolds
Regulatory Affairs Consultant
Proxima Clinical Research
2450 Holcombe Boulevard
HOUSTON, TEXAS 77021

July 18, 2024

Re: K241879
Trade/Device Name: vRad Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 26, 2024
Received: June 28, 2024

Dear Ellie Reynolds:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241879

Device Name

vRad Viewer

Indications for Use *(Describe)*

The vRad Viewer software is used with general purpose computing hardware which meets or exceeds minimum specifications. The vRad Viewer is intended to receive, display, and transmit images for clinical purposes. The vRad Viewer is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with storage components. The vRad 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 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 Viewer 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 may only be used on monitors determined to be appropriate for the desired task.

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

510(k) Owner:	Virtual Radiologic Corporation 11995 Singletree Lane Eden Prairie, MN 55344
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Representative Consultant Contact:	Ellie Reynolds, MBE Proxima Clinical Research, Inc. 2450 Holcombe Blvd, Suite J Houston, TX 77021 Telephone: +1-214-213-0611 E-mail: Ellie@ProximaCRO.com
Date Summary Prepared:	18 July 2024
Trade Name:	vRad Viewer
Common Name:	System, Image Processing, Radiological
Classification:	Class II
Classification Number:	21 CFR 892.2050
Product Code(s):	LLZ
Classification Advisory Committee:	Radiology

Predicate Device(s):	vRad PACS with Mammography (K162145)

Device Description:

The vRad Viewer is a Software as a Medical Device (SaMD) that imports medical data in the Digital Imaging and Communications and Medicine (DICOM) standard from local storage or remote Picture Archiving and Communications System (PACS) sources. The vRad Viewer is a modified version of the Viewer component cleared as part of vRad PACS with Mammography (K162145). Like the Viewer component of the vRad PACS with Mammography device, the vRad Viewer is intended to allow users to visualize, manipulate, and interpret medical images from X-ray radiography, X-ray computed tomography, MRI, ultrasound, nuclear medicine, and other DICOM-compliant modalities on compatible PC workstations. The vRad Viewer is designed to interface with radiologist workflow applications, such as PACS or caching applications, as well as operate as a standalone image viewer.

The vRad Viewer allows users to perform operations related to the manipulation, enhancement, compression, and quantification of medical images at the command of the operator and based on user preferences. Other workflow tools (e.g., Color Map, Window Level Presets, Overlay Display Schemes) exist within the Viewer to allow for operator customization of display and usage preferences.

The Viewer is a Microsoft Windows-based software application that runs on “off-the-shelf” computers that meet the specified minimum basic computer configuration for the Viewer and are running Microsoft Windows 10 Operating System (OS). For operator input and control of the software, standard Microsoft Windows-compatible input devices are used, including keyboards of various configurations, multi-button mice, grips, foot pedal controls, the Contour ShuttlePRO (Jog-Dial), etc. The vRad Viewer is not a hardware device; however, a monitor is required to display images and to interface with the software. Image quality may vary depending on the display monitor, and users must utilize a compatible monitor that meets technical specifications required for the tasks intended to be performed by the user.

Intended Use / Indications for Use:

The vRad Viewer software is used with general purpose computing hardware which meets or exceeds minimum specifications. The vRad Viewer is intended to receive, display, and transmit images for clinical purposes. The vRad Viewer is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications and networked with storage components. The vRad 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 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 Viewer 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 may only be used on monitors determined to be appropriate for the desired task.

Technological Characteristics:

The technological characteristics of the vRad Viewer are substantially equivalent to the technological characteristics of the predicate device. Both devices may be used to evaluate the same imaging types, provide on-demand access to the image database, and provide image manipulation, annotation, and processing functions. Both devices may also be used to review reports, identify key images, and link a series of images. The predicate device differs from the vRad Viewer in that it consists of 3 primary components: Viewer, Storage, and Cache, while the vRad Viewer only contains the Viewer component. Other minor differences of the vRad Viewer include additional annotation and image viewing tools that are not present in the predicate device and updated operating system and web browser compatibility. Nevertheless, any differences in technological characteristics between the vRad Viewer and the predicate device do not raise any new and different questions in safety and effectiveness, and device performance has been verified through testing.

Software Testing:

The software used in the vRad Viewer has been determined to require a Basic Level of Documentation. Software verification and validation testing were conducted, and documentation has been provided in accordance with FDA Guidance Document, “Content of Premarket Submission for Device Software Functions.”

Cybersecurity Testing:

Cybersecurity testing for the vRad Viewer was conducted, and documentation has been provided in accordance with FDA Guidance Documents, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” and “Select Updates for the Premarket Cybersecurity Guidance: Section 524B of the FD&C Act.”

Conclusion:

In conclusion, the vRad Viewer is demonstrated to be as safe and effective as the identified predicate device. The vRad Viewer has the same intended use, principles of operation, and technological characteristics as the identified predicate device. Any minor differences in technological characteristics do not raise new or different questions regarding its safety and effectiveness when used as labeled. Software and cybersecurity testing demonstrate that the device performs as expected. Thus, the vRad Viewer is substantially equivalent to the identified predicate device.