RadUnity Corp.
% James Luker
Sr. Regulatory Consultant
Innolitics
1101 West 34th St
#550
Austin, Texas 78705

November 26, 2024

Re: K242810
Trade/Device Name: RadUnity (Version 1.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 15, 2024
Received: September 18, 2024

Dear James Luker:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242810

Device Name
RadUnity (Version 1.0.0)

Indications for Use *(Describe)*

RadUnity receives medical images from CT imaging acquisition devices adhering to the DICOM protocol for image transfer. RadUnity performs image management and digital image processing (centralized specification and reformatting) on the data. The processed images are transferred using the DICOM protocol to other devices supporting this standard protocol.

RadUnity is indicated for use by qualified radiology professionals and specialists.

RadUnity is not intended for primary diagnostic review.
RadUnity is not intended for mammographic image review or interpretation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

RadUnity	**RadUnity (Version 1.0.0)** **510(k) Summary** **(Per 21 CFR 807.92)**

1. CONTACT INFORMATION

Company Name	RadUnity Corp.
Address	2127 Regent Street Madison WI 53726
Phone Number	716 560 7751
Fax Number	N/A
Company Representative	Timothy Szczykutowicz
Email	tim@radunity.com
Primary Contact	Timothy Szczykutowicz
Primary Contact Phone Number	716 560 7751
Primary Contact Email	tim@radunity.com
Date Summary Prepared	August 8, 2024

2. DEVICE INFORMATION

Trade Name	RadUnity (Version 1.0.0)
Common Name	Radiologic image processing system
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Regulation Name	Medical image management and processing system
Class	2
Review Panel	Radiology

3. PRIMARY PREDICATE DEVICE INFORMATION

Predicate Device Name	AquariusAPS Server
Predicate Device K Number	K061214
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Regulation Name	Picture Archiving and Communications System
Class	2
Review Panel	Radiology

4. SECONDARY PREDICATE DEVICE INFORMATION

Predicate Device Name	Centricity PACS-IW with Universal Viewer
Predicate Device K Number	K123174
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Regulation Name	Picture Archiving and Communications System
Class	2
Review Panel	Radiology

5. DEVICE DESCRIPTION

RadUnity is stand-alone software device (SaMD) which allows centralized specification, management, standardization, and networking of CT images. RadUnity's software ingests DICOM CT image data and reformats them according to predefined user preferences.

Radunity processes industry standard DICOM imaging studies. Currently, the RadUnity solution only processes computed tomography (CT) images. The data may flow into the system from PACS, a post-processing system, or any DICOM node (e.g., directly from a modality unit). The data is transferred for image processing and standardization. The data is then routed to user defined DICOM destinations and output in DICOM format.

RadUnity is fundamentally a workflow management system which performs image processing and standardization which allows the clinical user to view the CT images with consistent formatting.

RadUnity provides the user with the ability to duplicate current clinical workflow steps required to generate images for qualified clinician interpretation that may involve automatic or manual steps. The RadUnity solution requires manual user interaction to generate and route images to DICOM destinations for qualified clinician interpretation.

The input DICOM images needed for RadUnity are referred to as “source volumes”. These source volumes are commonplace in the radiology community today (e.g., lung or bone reconstructions) and contain the needed information to create soft tissue and other thicker slice and lower resolution image volumes.

6. SUBJECT DEVICE INTENDED USE/INDICATIONS FOR USE

RadUnity receives medical images from CT imaging acquisition devices adhering to the DICOM protocol for image transfer. RadUnity performs image management and digital image processing (centralized specification and reformatting) on the data. The processed images are transferred using the DICOM protocol to other devices supporting this standard protocol.

RadUnity is indicated for use by qualified radiology professionals and specialists.

RadUnity is not intended for primary diagnostic review.
RadUnity is not intended for mammographic image review or interpretation.

7. SUBJECT DEVICE CONTRAINDICATIONS FOR USE

RadUnity has no specific contraindications.

However, the following Precautions are applicable to RadUnity:

- The RadUnity Graphic User Interface (GUI) is not intended for primary diagnostic review,
- RadUnity is not intended for mammographic image review or interpretation,
- RadUnity should not not be used outside of its stated Intended Use/Indications for Use,

- Users should not attempt to circumvent RadUnity cybersecurity controls,
- RadUnity should not be used for real-time imaging applications.
- RadUnity should not be used Use for non-CT imaging datasets,
- Source volume images must be axial CT images in Hounsfield units (i.e., no volume renderings, dual-energy material basis images, quantitative perfusion maps, sagittal/coronal/oblique plane images, MIP images, minIP images or any other images not containing axial CT image data in units of Hounsfield unit).

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

8.1. Primary Predicate Device Intended Use/Indications for Use

The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

8.2. Secondary Predicate Device Intended Use/Indications for Use

Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA.

Typical users of this system are trained professionals, including but not limited to radiologists,

physicians, nurses, medical technicians, and assistants.

8.3.Intended Use/Indications for Use Equivalence Discussion

Subject Device RadUnity (Version 1.0.0)	**Primary Predicate Device** Terarecon AquariusAPS Server (K061214)	**Secondary Predicate Device** GE Centricity PACS-IW (K123174)	**Equivalence Discussion**
RadUnity receives medical images from CT imaging acquisition devices adhering to the DICOM protocol for image transfer. RadUnity performs image management and digital image processing (centralized specification and reformatting) on the data. The processed images are transferred using the DICOM protocol to other devices supporting this standard protocol. RadUnity is indicated for use by qualified radiology professionals and specialists. RadUnity is not intended for primary diagnostic review. RadUnity is not intended for mammographic image review or interpretation.	The AquariusAPS server receives medical images from medical imaging acquisition devices adhering to the DICOM protocol for image transfer such as EBT, CT, MRI, and other volumetric or planar medical imaging modalities, and performs digital image processing to derive certain information or new images from these image sets. The information or new images thus derived is transmitted using the DICOM protocol to other devices supporting this standard protocol. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed	Centricity PACS-IW with Universal Viewer is a device that displays medical images (including mammograms) and data from various imaging sources. Images and data can be viewed, communicated, processed and displayed within the system or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Megapixel resolution and meet other technical specifications reviewed and accepted by the FDA. Typical users of this system are trained professionals, including	**Equivalent to Primary Predicate Terarecon AquariusAPS Server (K061214)-** The subject RadUnity device and the primary predicate device AquariusAPS server are intended to receive, process and transfer DICOM CT images using the DICOM protocol. The AquariusAPS server is intended to receive, process, manage and transfer DICOM images from additional imaging modalities such as EBT, CT, MRI and other volumetric or planar medical imaging modalities. RadUnity is not intended for use for these additional DICOM imaging modalities. Additionally, RadUnity does not process raw sinogram or projection data from CT images which is equivalent to the AquariusAPS server RadUnity functions in an equivalent manner in terms of safety and effectiveness to AquariusAPS server in the receipt, processing, management and transferring of DICOM CT images. RadUnity and the

	and accepted by FDA.	but not limited to radiologists, physicians, nurses, medical technicians, and assistants.	AquariusAPS server are intended to provide pre-processing of images and to remove the need for an image review system to perform these activities. This is a primary area of equivalence to the AquariusAPS server primary predicate device. RadUnity includes the ability to view images in order to facilitate the processing functionality but is not intended to be used as the primary review software. The PACS system which receives the processed images from RadUnity is intended for the diagnostic review aspect. This is equivalent to the AquariusAPS server in terms of functionality, safety and effectiveness. RadUnity is not intended for mammographic image review or interpretation. The AquariusAPS server is intended for interpretation of mammographic images under specific circumstances. RadUnity's clinical workflow does not include review/interpretation of mammographic images. Therefore, the lack of mammographic image review/interpretation functionality does not change RadUnity's intended use in relation to the primary predicate device or raise different questions of safety or effectiveness as compared to the Aquarius predicate device.

			Equivalent to Equivalent to Primary Predicate GE Centricity PACS-IW (K123174)- The Centricity PACS-IW with universal viewer secondary predicate device is intended to communicate, process and display DICOM CT images (and other DICOM modalities) and transfer the images via the DICOM protocol via the network. Therefore, RadUnity and the secondary predicate Centricity PACS-IW with universal viewer share the same intended use. The Centricity PACS-IW with universal viewer device supports additional DICOM imaging modalities and image review functionality that are not needed by RadUnity to accomplish it's intended use in a safe and effective manner. The Centricity PACS-IW with universal viewer secondary predicate device includes the technological characteristic of 'Smart Reading Protocols (SPR)'. This characteristic allows the user to set the image 'view' for source volumes and then apply the view to future images. This technologic characteristic is equivalent to RadUnity's 'Profiles' which allows the user to configure source volume specific profile mapping and apply it to future images. This characteristic is the reason for selecting the Centricity PACS-IW with universal viewer as a secondary predicate device.

			RadUnity and the Centricity PACS-IW with universal viewer device have an equivalent intended use. The differences do not raise different questions of safety or effectiveness.

8.4. Predicate Device Comparison Table

Characteristic	**RadUnity** (Version 1.0.0)	**AquariusAPS server (K061214) (Primary Predicate)**	**Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)**	**SE Discussion**
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Same
Regulation Name	Medical image management and processing system	Picture archiving and communications system	Picture archiving and communications system	FDA regulation name has changed for 21 CFR 892.2050 from 'Picture archiving and communications system' to 'Medical image management and processing system'. The update in name does not fundamentally change the purpose/intended use of the associated medical devices.
Product Code	LLZ	LLZ	LLZ	Same
Regulatory Class	2	2	2	Same
Submission type	510(k)	510(k)	510(k)	Same
GMP Exempt	No	No	No	Same

Characteristic	**RadUnity** (Version 1.0.0)	**AquariusAPS server (K061214) (Primary Predicate)**	**Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)**	**SE Discussion**
Technological Characteristics Comparison				

Characteristic	**RadUnity** (Version 1.0.0)	**AquariusAPS server (K061214) (Primary Predicate)**	**Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)**	**SE Discussion**
Device Type	Software medical Device (SaMD)	Software medical Device (SaMD)	Software medical Device (SaMD)	Same- Both the subject and predicate devices are SaMD
Operating Environment	Local web browser-based user-facing application, network server for image processing utilizing commercially available computer platforms and operating systems.	Locally installed user-facing application, network server for image processing utilizing commercially available computer platforms and operating systems.	Deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations and utilizes commercially available computer platforms and operating systems.	Equivalent- RadUnity utilizes a locally installed Web browser based user-facing graphical user interface (GUI) which communicates to a local image processing server. This configuration is equivalent to the primary and secondary predicate device operating environment configurations. There may be minor differences between RadUnity and the predicate devices for this technological characteristic. However, these do not raise any different questions on safety of effectiveness of the RadUnity device as compared to the predicate devices.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Computer Hardware	RadUnity software runs on industry standard computer hardware which meets the minimum specification.	AquariusAPS server software runs on industry standard computer hardware which meets the minimum specification.	Centricity PACS-IW with universal viewer server software runs on industry standard computer hardware which meets the minimum specification	Equivalent- The subject RadUnity device and the predicate devices utilize commercially available computer platforms and operating systems. The specifics may differ to some degree based on the timeframes in which the predicate devices were cleared. However, this does not raise any different questions on safety of effectiveness of the device.
Operating Systems Supported	Computer running Microsoft Windows 10/11 with Microsoft Edge (minimum supported version 128) and Google Chrome browsers (minimum version 126)	Microsoft Windows, Internet Explorer	Microsoft Windows, Internet Explorer	Equivalent- The RadUnity subject device, the primary and secondary predicate devices utilize the Microsoft Windows OS as well as an Internet Browser. The subject RadUnity versions are more current than the predicate's due to the timeframe that the devices were cleared. However, this does not raise any different questions on safety of effectiveness of the RadUnity device.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Graphic User Interface	Web browser based	Web browser based	Web browser based	Equivalent- The subject RadUnity device as well as the primary and secondary predicate devices utilize a Web-based browser. There may be minor differences for this technological characteristic between RadUnity and the predicate devices. However, these do not raise any different questions on safety of effectiveness.
Image input type	DICOM CT images	DICOM CT, EBT, MRI and other volumetric or planar images	DICOM CT, MRI, US, NM,CR,PET, DX, XA and other DICOM images	Equivalent- The subject RadUnity device is currently intended to use only DICOM CT images. The primary and secondary predicates include additional DICOM imaging modalities. RadUnity and the predicate devices are equivalent in terms of DICOM CT image input type. RadUnity's intended use does not require other DICOM image types. This difference does not raise any new questions of safety and effectiveness.

Characteristic	**RadUnity** (Version 1.0.0)	**AquariusAPS server (K061214) (Primary Predicate)**	**Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)**	**SE Discussion**
Interoperability	RadUnity receives (as input), CT images from CT acquisition devices which use DICOM transfer protocols. RadUnity transfers the processed images using DICOM transfer protocols	AquariusAPS server receives (as input), CT, EBT, MRI and other volumetric or planar medical imaging modalities, from imaging acquisition devices which uses DICOM transfer protocols. AquariusAPS server transfers the processed images using DICOM transfer protocols	Centricity PACS-IW with Universal Viewer receives (as input), CT, US, NM, MRI and other medical imaging modalities, from imaging acquisition devices which uses DICOM transfer protocols. Centricity PACS-IW with Universal Viewer is designed to be deployed over conventional TCP/IP networking infrastructure available in most healthcare organizations	Equivalent- RadUnity and the primary and secondary predicate devices are intended to receive DICOM CT images from image acquisition devices and transfer the processed images using the DICOM transfer protocol. There may be minor differences for this technological characteristic between RadUnity and the predicate devices. However, these do not raise any different questions on safety of effectiveness.
DICOM Tags	RadUnity is capable of performing actions based on DICOM tags contained in images	AquariusAPS server is capable of performing actions based on DICOM tags contained in images	Centricity PACS-IW with Universal Viewer is capable of performing actions based on DICOM tags contained in images	Equivalent- RadUnity and the primary and secondary predicate devices perform actions based on DICOM tags. There may be minor differences for this technological characteristic between RadUnity and the predicate devices. However, these do not raise any different questions on safety of effectiveness.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Image Presentation	RadUnity's Profile Builder user interface allows the user to control image generation and presentation settings.	AquariusAPS includes an 'Auto Batch' function which is used to automatically generate reformatted images.	Centricity PACS-IW with Universal Viewer, user interface allows the user to control image presentation and generation settings.	Equivalent- RadUnity and the primary (AquariusAPS) and secondary predicate (Centricity PACS-IW with Universal Viewer) have equivalent functionality in terms of image presentation/generation settings. There may be minor differences for this technological characteristic between RadUnity and the predicate devices. However, these do not raise any different questions on safety of effectiveness.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Image Management	RadUnity 'maps' profiles to specific exam types (e.g., by telling RadUnity the typical order/study description and scanner protocols used for the exam type) RadUnity allows the user to configure source volume specific profile mapping and apply it to future images. The user can also modify reconstruction extents (i.e., what part of a source volume is used for RadUnity processing for a specific profile reformat).	AquariusAPS server is capable of creating images and image sequences in a variety of formats. However, it is not known whether the AquariusAPS Server device is capable of applying those formats to future images.	The Smart Reading Protocols (SPR) within the Centricity PACS-IW with Universal Viewer allows the user to set the image 'view' for source volumes and then apply the view to future images.	Equivalent- RadUnity 's ability to configure source volume specific profile mapping is most equivalent to the secondary predicate's (Centricity PACS-IW) Smart Reading Protocols (SPR) as the setting for source volumes and the application of the setting(s) to future images is equivalent. The primary predicate (AquariusAPS server) can create image/sequences in a variety of formats. However, it is not known whether the Aquarius device is capable of applying those formats to future images. RadUnity's functionality is equivalent to the secondary predicate's as the outcome is essentially the same and therefore would be equivalent in terms of safety and effectiveness.

Characteristic	**RadUnity** (Version 1.0.0)	**AquariusAPS server (K061214) (Primary Predicate)**	**Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)**	**SE Discussion**
Image processing functionality	RadUnity has the following image processing functionality: ● Filtering ○ Smoothing ○ Edge Enhancement ● Multiplanar Reformating (MPR) ● Maximum Intensity Projection (MIP) ● Minimum Intensity Projection (MinIP)	AquariusAPS server has the following image processing functionality: ● Filtering ● Multiplanar Reformating (MPR) ● Maximum Intensity Projection (MIP) ● Minimum Intensity Projection (MinIP)	Centricity PACS-IW with Universal Viewer has the following image processing functionality: ● Edge enhancement ● Changing the image plane from one plane to another ● Multiplanar Reformatting (MPR) ● Maximum Intensity Projection (MIP) ● Minimum Intensity Projection (MinIP)	Equivalent- The subject RadUnity device and the predicate devices have equivalent imaging processing functionality. Minor differences do not raise any new questions of safety and effectiveness.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Image Export	RadUnity is capable of exporting reformatted images and image sequences to DICOM capable destinations	AquariusAPS server is capable of exporting reformatted images and image sequences to DICOM capable destinations	Centricity PACS-IW with Universal Viewer is capable of exporting reformatted images and image sequences to DICOM capable destinations	Equivalent- The subject RadUnity device and the primary AquariusAPS server are intended to perform image processing/reformatting and transfer the images via the DICOM protocol to an image review system. The secondary Centricity PACS-IW with Universal Viewer device is also capable of exporting images and image sequences to DICOM capable destinations but includes an image review system. RadUnity and the primary (AquariusAPS) and secondary predicate (Centricity PACS-IW with Universal Viewer) have equivalent functionality in terms of image image/sequence exportation. There may be minor differences for this technological characteristic between RadUnity and the predicate devices. However, these do not raise any different questions on safety of effectiveness.

Characteristic	RadUnity (Version 1.0.0)	AquariusAPS server (K061214) (Primary Predicate)	Centricity PACS-IW with Universal Viewer (K123174) (Secondary Predicate)	SE Discussion
Automation functionality	RadUnity includes 'Profile' functionality which allows the user to set up the images in a user-preferred layout: layout, image series placement, automatic post-processing, etc..	AquariusAPS server includes 'Autobatch' functionality. AutoBatch generates reformatted images on CT data that has been pushed to the AquariusAPS server.	Centricity PACS-IW with Universal Viewer includes 'Smart Reading Protocols' (SRP). SRP's allow the user to set up the images in a user-preferred layout: viewports layout, image series placement, automatic post-processing, etc..	Equivalent- The subject RadUnity device's Profile' functionality is equivalent to the primary predicate AquariusAPS server's 'Autobatch' functionality and the secondary predicate Centricity PACS-IW with Universal Viewer's 'Smart Reading Protocols' functionality. The secondary predicate's 'Smart Reading Protocols' appear to be a closer match to RadUnity's 'Profiles' functionality than the primary predicate's 'Autobatch' functionality. The differences between RadUnity's and the 'Profiles' functionality and Centricity PACS-IW with Universal Viewer 'Smart Reading Protocols' do not raise new questions relating to safety or effectiveness.

9. PERFORMANCE DATA

9.1. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.

RadUnity includes Cybersecurity functionality and information which conforms to FDA's September 23, 2023 'Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions' guidance.

RadUnity conforms with DICOM standards (i.e., NEMA DICOM PS3.5 2024e).

RadUnity's validation activities included Usability validation testing which was performed by U.S. Board Certified Radiologists.

As the intended use, functionality and performance of the subject device and the predicate device are equivalent, the result of the performance testing is evidence that the RadUnity performs in an equivalent manner to the AquariusAPS Server primary predicate and secondary predicate devices.

9.2. Clinical Performance Testing

No clinical performance data was necessary to claim substantial equivalence.

10. CONCLUSION

The RadUnity device shares similar technological characteristics, intended use, and functionality with the predicate devices. There are no differences between the devices that raise new questions of safety and effectiveness.

Furthermore, non-clinical performance test data and software verification and validation demonstrate that RadUnity performs comparably to the predicate device in terms of safety and effectiveness.

Based on the device comparisons and the acceptable testing results, it is determined that RadUnity is substantially equivalent to the predicate devices.