April 23, 2026

CliniComp, Intl.
Dessi Lyakov
Director Quality and Regulatory Affairs
9655 Towne Centre Dr.
San Diego, CA 92121

Re: K254237
Trade/Device Name: Cci Pacs Viewer (PACS-US-001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 22, 2026
Received: March 23, 2026

Dear Dessi Lyakov:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

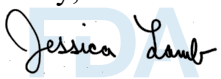
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254237

Please provide the device trade name(s).

CCI PACS VIEWER (PACS-US-001)

Please provide your Indications for Use below.

The CCI PACS VIEWER is a software-based Medical Image Management and Processing System (MIMPS) intended to archive, distribute, retrieve, process, and display medical images and associated data from DICOM-compliant modalities and hospital information systems.
The device provides healthcare professional tools to aid in the review, analysis, and interpretation of medical images through interactive display, manipulation, measurement, annotation, and comparison of images from supported modalities (CT, MR, PET, US, X-Ray).
It is intended for use by trained and licensed healthcare professionals whose scope of practice includes the review or interpretation of medical images. This includes radiologists for primary diagnostic interpretation, and physicians or qualified medical technicians for clinical review, analysis, and consultation. Users must have completed appropriate training on the software's functions, capabilities, and limitations.
The system supports visualization and qualitative assessment of anatomical structures across images from major modalities, including spatial review within a single study and side-by-side or linked comparison of serial examinations. It is designed to assist healthcare providers in conjunction with primary diagnostics performed by a certified radiologist, or during direct consultation with a radiologist. The software is not intended to replace the independent skill, judgment, or diagnosis of a qualified medical practitioner.
The device is not intended for primary diagnostic interpretation of mammography images or lossy compressed images that do not meet clinical quality requirements for the intended use.
The CCI PACS VIEWER operates on a cloud-based virtual platform with a Windows operating system and is accessible via compliant HTML5 browsers on desktop, laptop, or mobile tablet devices.
• For primary diagnostic interpretation, display monitors must be FDA-cleared for diagnostic use (where required by regulation) and maintained under a documented quality control program compliant with applicable standards.
• CCI PACS VIEWER application on mobile devices such as iPhones and iPads is not intended for diagnostic use.
Prescription device - Rx Only Federal law restricts this device to sale by or on the order of a healthcare practitioner.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92.

Date: 23 April 2026

Contact Details:

Applicant Details: CliniComp, Intl.

Applicant Adress: 9655 Town Centre Dr., San Diego, CA 92121

Applicant Phone Number: 800-350-8202

Applicant Contact: Dessi Lyakov

Applicant Contact Email: dessi.lyakov@clinicomp.com

Device:

Device Trade Name: CCI PACS VIEWER (PACS-US-001)

Classification Name: Medical image management and processing system

Common Name: Automated Radiological Image Processing Software

Regulation Number: 21 CFR 892.2050

Product Code(s): LLZ

Legally Marketed Predicate Device:

Predicate Device: IBM iConnect Access, K203104 Product Code: LLZ, Regulation Number: 21 CFR 892.2050

Reference Device: OmegaAI Image Viewer, K222476, Product Code: LLZ, Regulation Number: 21 CFR 892.2050

Device Description Summary:

The CCI PACS VIEWER is a Class II Medical Image Management and Processing System (MIMPS) as defined under 21 CFR 892.2050.

The CCI PACS VIEWER is a software-based Medical Image Management and Processing System (MIMPS) that provides visualization, review, processing, and basic analysis tools for digital medical images and associated data acquired from DICOM-compliant modalities, including CT, MRI, PET, Ultrasound (US), and X-Ray.

The device supports the display and qualitative assessment of anatomical structures and tissues across a broad range of body regions and organ systems typically imaged in general radiology practice, such as: Head and neck, chest and thorax, abdomen and pelvis, musculoskeletal system, vascular structures.
Note that no tissue types or anatomical structures are explicitly excluded when imaged by supported modalities, provided the images are DICOM-compliant and contain valid metadata for display and rendering.

It enables visualization of anatomical features and any observable changes in these structures across serial imaging studies (temporal comparison) or within a single study (spatial assessment), including tools for measurement, annotation, window/level adjustment, zooming, multi-planar reconstruction (MPR), and basic image enhancement/processing to aid trained professionals in diagnostic review.

The device is not intended for:

- Advanced quantitative tissue characterization (e.g., perfusion analysis, spectroscopy, or texture-based lesion typing)
- Primary interpretation of mammography images (unless specifically validated and cleared for that use)
- Automated detection, segmentation, or diagnosis of specific pathologies or tissue abnormalities

Visualization and assessment capabilities are limited to those provided by standard DICOM viewing and processing functions, without proprietary algorithms for tissue-specific change quantification beyond basic comparison tools. Visualization and assessment capabilities are limited to those provided by standard DICOM viewing and processing functions, without proprietary algorithms for tissue-specific change quantification beyond fundamental comparison tools.

Intended Use:

The CCI PACS VIEWER is a software-based Medical Image Management and Processing System (MIMPS) intended to provide a centralized platform for the electronic archive, distribution, retrieval, processing, and display of medical images and associated data. It serves as a diagnostic and clinical review interface for DICOM-compliant modalities and hospital information systems, facilitating the management of patient imaging data across a healthcare enterprise.

Indications for use:

The CCI PACS VIEWER is a software-based Medical Image Management and Processing System (MIMPS) intended to archive, distribute, retrieve, process, and display medical images and associated data from DICOM-compliant modalities and hospital information systems.

The device provides healthcare professional tools to aid in the review, analysis, and interpretation of medical images through interactive display, manipulation, measurement, annotation, and comparison of images from supported modalities (CT, MR, PET, US, X-Ray).

It is intended for use by trained and licensed healthcare professionals whose scope of practice includes the review or interpretation of medical images. This includes radiologists for primary diagnostic interpretation, and physicians or qualified medical technicians for clinical review, analysis, and consultation. Users must have completed appropriate training on the software's functions, capabilities, and limitations.

The system supports visualization and qualitative assessment of anatomical structures across images from major modalities, including spatial review within a single study and side-by-side or linked comparison of serial examinations. It is designed to assist healthcare providers in conjunction with primary diagnostics performed by a certified radiologist, or during direct consultation with a radiologist. The software is not intended to replace the independent skill, judgment, or diagnosis of a qualified medical practitioner.

The device is **not** intended for primary diagnostic interpretation of mammography images or lossy compressed images that do not meet clinical quality requirements for the intended use.

The CCI PACS VIEWER operates on a cloud-based virtual platform with a Windows operating system and is accessible via compliant HTML5 browsers on desktop, laptop, or mobile tablet devices.

- For primary diagnostic interpretation, display monitors must be FDA-cleared for diagnostic use (where required by regulation) and maintained under a documented quality control program compliant with applicable standards.
- CCI PACS VIEWER application on mobile devices such as iPhones and iPads is not intended for diagnostic use.

Prescription device - Rx Only Federal law restricts this device to sale by or on the order of a healthcare practitioner.

Comparison with predicate and reference devices:

The detailed analysis of the subject device and the primary and secondary predicate devices (shown in the Device comparison table) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the primary predicate (K203104) and with the secondary predicate (K222476). Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since the subject device and both predicate devices are software as a medical device application with no tangible component interfacing with the body.

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
Device	CCI PACS VIEWER	IBM iConnect Access	OmegaAI Image Viewer
510(k) number	254237	K203104	K222476
US FDA Risk Class of Device	II	II	II
Product Code	LLZ	LLZ	LLZ
Product Regulation	21 CFR §892.2050	21 CFR §892.2050	21 CFR §892.2050
Device	System, image processing, radiological	System, image processing, radiological	System, image processing, radiological
Regulation Description	Medical image management and processing system.	Medical image management and processing system.	Medical image management and processing system.
Intended Use / Indications for Use	The CCI PACS VIEWER is a software-based Medical Image Management and Processing System (MIMPS) intended to archive, distribute, retrieve, process, and display medical images	The IBM iConnect Access application provides internet access to multi-modality softcopy medical images, reports, and other patient-related information to	OmegaAI Image Viewer is software for diagnostic and clinical review intended for use in General Radiology (images from modalities including CR, CT, DX, MR, MG, NM, US, PET,

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
	and associated data from DICOM-compliant modalities and hospital information systems. The device provides healthcare professional tools to aid in the review, analysis, and interpretation of medical images through interactive display, manipulation, measurement, annotation, and comparison of images from supported modalities (CT, MR, PET, US, X-Ray). It is intended for use by trained and licensed healthcare professionals whose scope of practice includes the review or interpretation of medical images. This includes radiologists for primary diagnostic interpretation, and physicians or qualified medical technicians for clinical review, analysis, and consultation. Users must have completed appropriate training on the software's functions, capabilities, and limitations.	conduct diagnostic review, planning and reporting through the interactive display and manipulation of medical data. IBM iConnect Access provides healthcare professional tools to aid in interpreting medical images including: • Displaying DICOM compliant medical images and non-DICOM content using XDS • Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images • Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/ level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path. • Creating individually	RG, SC, VL, XA, Film Digitizer), Interventional Radiology, cardiology, oncology, obstetrics and gynecology, gastroenterology, ENT, orthopedics, internal medicine, emergency medicine, dermatology, dentistry, cardiology, rheumatology, Pathology (i.e., to review captured images/videos from a sample) and other healthcare imaging applications. OmegaAI Image Viewer is intended to be used with off the shelf computing devices. Display monitors used for reading medical images for diagnostic purposes must comply with applicable clinical requirements, regulatory approvals and with quality control requirements for their use and maintenance. With appropriate display monitors, lighting, image quality, and level of lossy image compression, the

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
	The system supports visualization and qualitative assessment of anatomical structures across images from major modalities, including spatial review within a single study and side-by-side or linked comparison of serial examinations. It is designed to assist healthcare providers in conjunction with primary diagnostics performed by a certified radiologist, or during direct consultation with a radiologist. The software is not intended to replace the independent skill, judgment, or diagnosis of a qualified medical practitioner. The device is **not** intended for primary diagnostic interpretation of mammography images or lossy compressed images that do not meet clinical quality requirements for the intended use. The CCI PACS VIEWER operates on a cloud-based virtual platform with a Windows	captured DICOM images that can be displayed and stored in a PACS • Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms. • Creating and outputting digital files suitable for the fabrication of physical replicas, such as 3D printing, using DICOM files as inputs. Physical/3D printed models generated from the digital output files are not for diagnostic use. The IBM iConnect Access application can be configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data	OmegaAI Image Viewer is intended for diagnostic purposes (on desktop platforms) and as a non-diagnostic review tool (on mobile platforms) to be used by trained healthcare professionals. Display calibration and lighting conditions should be verified by viewing a test pattern prior to use for diagnostic purposes. OmegaAI Image Viewer supports major desktop and mobile browsers such as Microsoft Edge, Chrome, Safari, Apple iOS, Android, Windows. OmegaAI Image Viewer displays both lossless and lossy compressed images. Each healthcare professional must ensure that they have the necessary environment to ensure the appropriate image quality for their clinical purpose and determine the level of lossy image compression acceptable for their purpose. Lossy image

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
	operating system and is accessible via compliant HTML5 browsers on desktop, laptop, or mobile tablet devices. • For primary diagnostic interpretation, display monitors must be FDA-cleared for diagnostic use (where required by regulation) and maintained under a documented quality control program compliant with applicable standards. • CCI PACS VIEWER application on mobile devices such as iPhones and iPads is not intended for diagnostic use. Prescription device -Rx Only Federal law restricts this device to sale by or on the order of a healthcare practitioner.	compression that is suitable for their purpose. 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 MP resolution and meets other technical specifications reviewed and accepted by FDA. Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Use of IBM iConnect Access application on mobile devices such as iPhones and iPads is not intended for diagnostic use	compression should not be used for primary reading in mammography. OmegaAI Image Viewer can be utilized for image manipulation by radiology technologists or other healthcare professionals. OmegaAI Image Viewer can be used to verify images that are captured in a medical imaging system have a diagnostic quality, to correct viewing characteristics of the image such as orientation, rotation, contrast, as well as to add annotations to mark significant finding or provide guidance for radiologists. OmegaAI Image Viewer can store annotations and measurements as DICOM presentation states without changing the original image data. OmegaAI Image Viewer can display annotations and

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
			measurements as an overlay on images from DICOM objects, and from Computer-Aided Diagnosis (CAD) and AI software. The viewer can perform 3D Multi-Planar Reformatting (MPR), 3D Maximum Intensity Projection (MIP) and 3D Volume Rendering (VR). OmegaAI Image Viewer is purposed to aid in reviewing findings through its ability to display clinical documents and reports side by side with the images. This can be used side by side with a reporting tool to create diagnostic reports. Note: To protect confidential information and ensure data security, the OmegaAI Image Viewer has User Access Control (UAC) which prevents unauthorized access and modification of data. OmegaAI Image Viewer runs in a web browser sand-box, thus it relies on the browser's handling of

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
			interruptions, low-memory conditions etc. The browser will give an error to the user when it is not able to perform due to an interruption. Caution: Federal law restricts this device to sell by or on the order of a physician.
PACS Functionality			
Fundamental PACS Functions	Display, process and analyze DICOM compliant medical images. Performs standard PACS functions with respect to querying and listing	Yes	Yes
Computer Platform / Computer operating system	Standard off-the-shelf PC workstation Windows OS	Yes	Yes
	Virtual Platform	Yes	Yes
Mobile Platforms	For nondiagnostic purposes; can be used as a review tool	No	Yes
Stand-alone software	Yes	Yes	Yes
HIPAA Compliance	The Viewer securely connects to the PACS using HTTPS. Images stay in the PACS, not on the device. When the web browser or mobile application is closed, all images and	Yes	Yes

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
	information are gone from the device. It does not store images on any user's device.		
DICOM Compliance	DICOM 3.1 NEMA PS 3.1 - 3.20 2024e	Yes	Yes
Functional Overview	Supports multi-modality DICOM display and manipulation for anatomical review in digital images captured by CT, MRI, PET, US, X-Ray. CCI PACS provides viewing and quantification.	Yes	Yes
Data Acquisition	Receives medical image data from DICOM compliant imaging devices and modalities.	Yes	Yes
	Receives medical image data from non DICOM sources.	Yes	Yes
Data/Image Types	Computed Tomography (CT)	Yes	Yes
	Magnetic Image Resonance (MRI)	Yes	Yes
	X-Ray	Yes	Yes
	US	Yes	Yes
	PET	Yes	Yes
Acquisition and	The medical modalities of these medical imaging systems	CT, MR, CR, US, NM, PT, and XA	The medical modalities of these medical imaging

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE PREDICATE
Modalities Features	include CT, MR, X-Ray, US, PET as supported by ACR/NEMA DICOM 3.0.		systems include, but are not limited to, CT, MR, CR, DX, MG, US, SPECT, PET and XA as supported by ACR/NEMA DICOM 3.0
2D Imaging	Yes	Yes	Yes
2D Measurement	Yes	Yes	Yes
3D Imaging	Review of structures in 3D	Yes	Yes
Measurement Tools			
Distance (length, diameter, perimeter)	Yes	Yes	Yes
Region of interest (ROI) and Volumetry (including SUV for PET images	Yes	Yes	Yes
Visualization/rendering			
2D	Yes	Yes	Yes
3D	Yes	Yes	Yes
MPR	Yes	Yes	Yes
Annotations	Yes	Yes	Yes
Structured Reporting	No	Yes	Yes

Performance Testing

Software verification and validation activities for CCI PACS VIEWER were performed in accordance with FDA guidance, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (June 2023), including measurement accuracy and usability tests.

The documentation provided in this application meets the Basic level definition.

Methodologies and Accuracy Specifications Measurements rely on DICOM metadata (primarily the Pixel Spacing attribute (0028,0030) for conversion to physical units in millimeters) and user placement of points/ROIs. All tools have been validated using non-clinical bench testing with de-identified clinical datasets across supported modalities (CT, MR, US, X-Ray, PET).

Accuracy specifications (verified under standard conditions, including calibrated Pixel Spacing and typical zoom/window-level settings):

- Linear Distance: ±0.1 mm or ±1 pixel (whichever is greater).
- Area Measurements: ±5% for area and mean pixel values (e.g., HU in CT).
- Angle Measurements: ±1 degree.
- ROI Statistics (e.g., mean HU): ±2% for uniform regions.

These specifications are acceptance criteria used during design verification and validation (traceable to internal V&V protocols). Results confirmed compliance with these limits across representative use cases.

CliniComp, Intl. has implemented security features for the device and data protection. Cybersecurity requirements, risk analysis, and mitigation were addressed in accordance with FDA guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission (June 2025). Furthermore, CCI PACS VIEWER adheres to recognized voluntary standards: DICOM (PS 3.1-3.20) for image communication and HL7 for healthcare data exchange. Compliance is further demonstrated through software verification and validation in accordance with IEC 62304:2006/Amd 1:2015 and risk management per ISO 14971:2019.

No clinical testing was required to demonstrate safety or effectiveness for the subject device as the device's non-clinical (bench) testing was sufficient to support the intended use of the device.

Evaluation of Similarities and Difference in Technical Performance with Respect to the Predicate Device*:*

There are no differences in Technical Performance as CCI PACS is as safe and effective, and is substantially equivalent to the IBM iConnect Access, K203104 legally marketed device (section 513(i)(1)(A) FD&C Act).

The detailed analysis of the subject device and the primary and secondary predicate devices (shown in the Device comparison table) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the primary predicate (K203104) and with the secondary predicate/reference device (K222476). Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since the subject device and both predicate devices are software as a medical device application with no tangible component interfacing with the body.

The non-clinical performance testing for the CCI PACS VIEWER demonstrates that the device meets all predetermined functional and technical specifications. Comprehensive software verification and validation activities, conducted in accordance with IEC 62304 (Class B), confirm that the system's advanced processing features, including 3D rendering and DICOM/HL7 interoperability—operate reliably within the defined hospital network environment. All identified software hazards have been successfully mitigated through rigorous architectural design and technical controls. Consequently, the non-clinical data provides objective evidence that the device is as safe and effective as the predicate and is suitable for its intended use.

The clinical evaluation of the CCI PACS VIEWER confirms that the system provides high-fidelity diagnostic image display and processing consistent with standard radiological workflows. By successfully fulfilling the requirements of ISO 14971:2019, the risk management process has demonstrated that the clinical benefits of improved image accessibility, 3D visualization, and integrated HL7 data exchange significantly outweigh any residual risks. The mitigations applied to the 140 identified hazards ensure that the potential for misdiagnosis or data corruption is minimized to an acceptable level. Based on the successful validation of the CCI PACS VIEWER Software Architecture against clinical user needs, it is concluded that the device's clinical benefit profile supports a finding of substantial equivalence.

Based on the results of the comprehensive Risk Management Report, the clinical benefits of the CCI PACS VIEWER—specifically its ability to provide timely, accurate, and interoperable medical image processing—outweigh the residual risks. All risks have been reduced to as low as reasonably practicable (ALARP), and the device performs as intended without compromising the safety of patients or end users.

Conclusion:

Nonclinical bench performance testing (including accuracy verification for measurement tools, display fidelity, and DICOM compliance) demonstrates that the CCI PACS VIEWER is as safe and effective as the predicate device (IBM iConnect Access, K203104) and performs equivalently in key technological characteristics. No clinical testing was required, as the device is a general-purpose MIMPS viewer with no novel diagnostic claims. Based on

the nonclinical data, intended use alignment, and technological comparison, the CCI PACS VIEWER is substantially equivalent to the predicate device.