Aikenist Technologies Pvt Ltd
% David Dills
Regulatory Consultant
David Dills
5450 Ariva Way
#302
Lakeland, Florida 33812

February 21, 2025

Re: K242838
Trade/Device Name: QuickRad
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 19, 2024
Received: January 23, 2025

Dear David Dills:

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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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)*

K242838

Device Name

QuickRad

Indications for Use *(Describe)*

QuickRad is a web-based PACS intended for use in radiology centers, diagnostic labs, and hospitals. It is designed to receive, store, transmit, process, and display medical images and associated data from various DICOM-compliant sources, including CT scanners, MRI systems, ultrasound machines, and X-ray devices. The system enhances communication and accessibility by allowing distributed access to images and data across computer networks. QuickRad also offers optional integration with FDA-cleared third-party AI models, enabling the visualization of AI-generated outputs. The system displays these outputs "as-is," with the safety and effectiveness of the AI models being covered under the original third-party manufacturer's regulatory clearance.Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA. The system is designed for utilization by proficient and certified medical practitioners, including physicians, radiologists, and medical technicians.

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.

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510(k) Summary

[AS REQUIRED BY 21CFR807.92]

I. APPLICANT INFORMATION

Submitter's Name	Aikenist Technologies Pvt. Ltd.
Submitter's Address	007, Pushpanjali, 1st Cross, 1st Main Road, Chamarajpet, Bangalore 560018, India
Name of Contact Person	Ashwin Amarapuram Chandramouly
Designation	Director and CEO
Contact Number	+91 9845320314
Contact E-mail	ashwin@aikenist.com
Date of Summary Prepared	22 Jan 2025

II. DEVICE DETAILS

Device Trade Name	QuickRad
Regulation Name/ Device Common Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Device Class	Class 2
Product Code	LLZ

III. PREDICATE DEVICE DETAILS

Device Trade Name	Augmento
Device Manufacturer Name	DEEPTEK MEDICAL IMAGING PRIVATE LIMITED
510(k) Number	K222781
Regulation Number	21 CFR 892.2050
Device Class	Class 2
Product Code	LLZ

IV. DEVICE DESCRIPTION

QuickRad is a web-based PACS designed to optimize radiology workflows and enhance clinical efficiency. It allows seamless receipt, management, and processing of DICOM images from various modalities, including CT, MRI, ultrasound, X-ray, and more.

Key Features and Functions:

- **Comprehensive Radiology Management**: QuickRad provides end-to-end functionality for the storage, transmission, processing, and visualization of medical images, ensuring seamless collaboration across healthcare networks.
- **Zero Footprint Viewer (ZFP)**: QuickRad's ZFP viewer offers cross-platform accessibility without the need for additional native software installation. It is compatible with macOS, Windows, Ubuntu and Chrome, Edge, Firefox browsers.
- **Enhanced Viewer Options**: QuickRad ensures that all scans are displayed with true-to-source fidelity, offering optional FDA-cleared viewer integrations that enhance diagnostic accuracy.
- **Advanced 3D Viewer**: QuickRad's 3D viewer empowers radiologists with cutting-edge image analysis tools, including:
    - Smooth stack scrolling, zooming, panning, and reset options.
    - Measurement tools for length, angles, and annotations.
    - Advanced visualization techniques such as Multiplanar Reconstruction (MPR) and Maximum Intensity Projection (MIP).
    - PET scan mode with customizable contrast settings, annotation capabilities, and snapshot tools for enhanced diagnostic insights.
- **Smart Reporting Editor**: QuickRad includes a modality-specific report editor that simplifies report creation. Pre-built templates for various imaging studies ensure consistent and efficient report generation with voice-enabled editing features.
- **AI Integration**: QuickRad offers optional integration with FDA-cleared third-party AI models, allowing radiologists to review AI-generated results directly within the platform. The AI output is displayed alongside original images for confirmation by qualified medical professionals.
- **DICOM Compliance**: Fully compliant with DICOM standards, QuickRad guarantees secure and interoperable image and data exchange across systems, ensuring compatibility with a wide range of imaging devices.
- **Secure Data Transmission**: It adheres to strict security protocols, utilizing HTTPS, AES 256 encryption, and multi-factor authentication (MFA) for secure access.

V. INDICATIONS FOR USE

QuickRad is an advanced PACS solution, available for on-premise or cloud hosting. It receives medical images and data from various DICOM-compliant origins, such as CT, MR scanners, ultrasound systems, and X-ray machines. These images and data undergo storage, transmission, processing, and display within the system, fostering smooth communication and accessibility across distributed locations on computer networks. It provides optional integration with FDA-cleared 3rd party AI models. The solution only supports the visualization of outputs of 3rd party AI models "as-is". The safety and effectiveness of the 3rd party model are covered under the original 3rd party manufacturer's regulatory clearance. Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA. The system is designed for utilization by proficient and certified medical practitioners, including physicians, radiologists, and medical technicians.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATEDEVICE

Table 1. Summary of Technological Characteristics Comparison of DeepTek and QuickRad.

Sl. No	Features	Predicate Device-Augmento	Proposed Device- QuickRad	Remarks
General information				
1.	510(k) Number	K222781	K242838	-
2.	Manufacturer	DeepTek Medical Imaging Private Limited	Aikenist Technologies Private Limited	-
3.	Common Name	Medical image management and processing system	Medical image management and processing system	Same
4.	Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
5.	Classification	Class II	Class II	Same
6.	Regulation number	21 CFR 892.2050	21 CFR 892.2050	Same
7.	Product Code	LLZ	LLZ	Same
8.	Indications For Use	Augmento is a web-based PACS and radiology workflow management solution. It accepts digital images and data from various DICOM-compliant sources (i.e. CT scanners, MR scanners, ultrasound systems, RF Units, PET Units, computed & digital radiographic devices, secondary capture devices, imaging gateways, and other imaging sources). Images and data can be stored, communicated, processed, and displayed within the system and/or across computer networks at distributed locations. Only preprocessed DICOM "for presentation" images can be interpreted for primary image diagnosis in mammography. Lossy compressed images and digitized film screens of mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA. This system is meant to be used by trained and qualified medical professionals,	QuickRad is an advanced PACS solution, available for on-premise or cloud hosting. It receives medical images and data from various DICOM-compliant origins, such as CT, MR scanners, ultrasound systems, and X-ray machines. These images and data undergo storage, transmission, processing, and display within the system, fostering smooth communication and accessibility across distributed locations on computer networks. It provides optional integration with FDA-cleared 3rd party AI models. The solution only supports the visualization of outputs of 3rd party AI models “as-is”. The safety and effectiveness of the 3rd party model are covered under the original 3rd party manufacturer’s regulatory clearance. Mammographic images may only be interpreted using a monitor that meets the technical specifications identified by the FDA. The system is designed for utilization by proficient and	Same

		physicians, radiologists, nurses, and medical technicians.	certified medical practitioners, including physicians, radiologists, and medical technicians.	
9.	Prescription or OTC	Prescription	Prescription	Same
Specifications				
10.	Modalities	Various Image sources	Various image sources	Same
11.	Web browser software	Google Chrome, Mozilla, and Edge	Google Chrome, Mozilla, Edge,	Same
12.	Resolution	32-bit Color Display & 1920x1080	32-bit Color Display & 1920x1080	Same
13.	Image Storage	Yes	Yes	Same
14.	Software environment	OS: Windows 10	OS: Windows 11	Same
Functions				
15.	Main Functions	• Log In • Worklist – Search Filter • Worklist – Open image • Work list- study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Comparative study • Viewer – Rotation • MIP/MPR Reconstruction • Viewer – Reference line • Viewer – Sharpening	• Log In • Worklist – Search Filter • Worklist – Open image • Work list- study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Thumbnail view of the series • Viewer–Changing the layout • Viewer–Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/Stack/ Custom/ Annotation/ synchronized screening) • Viewer – Comparative study • Viewer – Rotation • Viewer- MIP/MPR Reconstruction • Viewer – Reference line • Viewer–Measurement- rectangular, ellipse, angle/cobb angle • Viewer – Cine/movie mode • Viewer- Overlaying/ Hide or display overlay • Viewer- Magnify • Viewer- Probe/HU	Similar[1]

		• Viewer – Measure • Viewer – Inverting imagecolor • Viewer – Cine • Viewer- Overlaying.	• Viewer- crop	
16.	3D Cursor	Yes	Yes	Same
17.	Optional Integration of FDA-cleared 3rd party AI models	Yes	Yes	Same
18.	Operation feature	Web environment-based PACS. Viewing and handling DICOM medical images. Review and report study located on a server.	Web environment-based PACS. Viewing and handling DICOM medical images. Review, modify, and approve the study located in a server.	Same

[1]Deep Tek's Augmento viewer offers a sharpening feature for enhanced image clarity, a specific function that QuickRad's viewer does not include.

QuickRad and DeepTek share extensive similarities in their core functionalities and capabilities. Both systems are designed to manage radiology workflows effectively, supporting various modalities, resolution, image storage, and adhering to DICOM standards. They provide essential features such as study viewers, study worklists, and software environments, making them comparable in many aspects.

Integration with AI models in QuickRad is optional, allowing users the flexibility to incorporate AI capabilities as needed. QuickRad supports the integration of the following FDA-cleared AI models from Qure AI, offering seamless functionality while displaying outputs "as-is":

- qXR: Chest X-ray interpretation (FDA 510(k) clearance: K231149)
- qCT LN Quant: Advanced lung nodule quantification for chest CT scans (FDA 510(k) clearance: K231149)
- qER: AI for triaging intracranial hemorrhage and other conditions in CT scans (FDA 510(k) clearance: K212624)

These integrations ensure compliance with regulatory standards while enhancing diagnostic capabilities.

A key difference is that DeepTek's Augmento viewer includes a sharpening feature to enhance image clarity, which is not available in QuickRad's viewer. Despite this distinction, QuickRad maintains substantial equivalence to DeepTek in terms of overall performance and functionality. QuickRad offers comparable capabilities with added flexibility and adaptability, catering to diverse user needs.

The absence of the sharpening feature in QuickRad does not affect its overall effectiveness and safety. QuickRad delivers robust performance with its flexible and adaptable platform, aligning well with DeepTek's offerings.

VII. NON-CLINICAL PERFORMANCE DATA

The non-clinical performance activities include:

- **Risk Management & Cybersecurity**
  - Device Hazard Analysis as per ISO 14971:2019
  - Vulnerability Assessment & Penetration Testing (VAPT) based on OWASP Top 10.
- **Usability Testing**
  - Formative and Summative Usability Testing per IEC 62366-1:2015
- **Software Verification & Validation**
  - Unit Testing based on Software Requirements Specifications (SRS)

    - Integration Testing for interaction between software components
    - System Testing covering end-to-end functionality
    - Validation based on User Requirements Specifications (URS)
- **Measurement Study**
    - Establishing equivalence with FDA-cleared viewer
- **3rd Party AI Model Integration Interface Testing**

Non-clinical testing consisted of:

- QuickRad underwent a thorough hazard analysis, addressing both intentional and unintentional risks in compliance with ISO 14971:2019. Strategies to mitigate these risks were implemented to ensure safety throughout the device lifecycle, and the hazard analysis and mitigation strategies were validated, confirming QuickRad's compliance with ISO 14971:2019.

- Periodic VAPT by third-party consultants were conducted to verify the adequacy of QuickRad's security controls, effectively mitigating potential cybersecurity risks.

- Usability testing, conducted in compliance with IEC 62366-1:2015, included both formative and summative evaluations.

- Unit testing verified core functional components were independently tested, ensuring QuickRad's units work as intended, with code correctness and completeness validated. Integration testing confirmed seamless interaction between software components and external systems, while system testing validated end-to-end functionality across all features. User Acceptance Testing verified QuickRad meets its intended use, ensuring adherence to the user requirement specifications documents through end-user validation. The test cases were addressed and successfully passed the acceptance criteria.

- Integration testing for QuickRad validated seamless end-to-end functionality across its software components, including APIs, OTS/SOUP components detailed in the SBOM, independent libraries, and DICOM interfaces. System testing encompassed core functionalities such as user management, DICOM viewer operations, search capabilities, radiologist assignment workflows, report management, audit log tracking, error handling, and hospital management, ensuring robust performance and compliance with the system's defined specifications.

- An angle measurement study was conducted using 12 X-ray images (AP Pelvic, AP Knee, Lateral Ankle), evaluated independently by two experienced radiologists. Angles spanning the 0° to 180° range were measured using QuickRad's Viewer and benchmarked against the FDA-cleared FlexView Diagnostic DICOM Viewer (K233226). Statistical analyses, including equivalence testing and T-tests, demonstrated that QuickRad's angle measurement tool is substantially equivalent to FlexView Diagnostic and produced clinically reliable angle assessments.

- A study was conducted to validate measurement tools in QuickRad's Viewer. Length, rectangle, ellipse ROI, and probe measurements were evaluated on CT abdomen images, while reference line accuracy was assessed using MR spine and brain images. This comprehensive evaluation, encompassing diverse imaging modalities, confirmed that QuickRad delivers performance equivalent to the FDA-cleared FlexView Diagnostic DICOM Viewer (K233226), ensuring consistent, reliable, and clinically accurate measurements across the spectrum of diagnostic imaging.

- The integration interface between QuickRad and 3rd party AI models were tested to confirm that the integrity of the source DICOM file and output from AI models is unaltered and hence, does not get impacted when the source file is sent to the AI model for findings and the AI model sends the output to QuickRad through the interface.

The standards applicable as per Recognized Consensus Standards are as follows:

- ISO 13485: 2016 Edition 3- Quality Management Systems for Medical Devices
- IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical device software - Software life cycle processes.
- IEC 62366-1:2015: Medical Devices 1: Application of usability engineering to medical devices.
- ISO 14971 Third Edition 2019-12 Medical Devices - Application of risk management to medical devices.
- NEMA PS 3.1 - 3.20 2023e Digital Imaging and Communications in Medicine (DICOM) Set.

- IEC ISO 10918-1 First edition 1994-02-15 Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including Technical Corrigendum 1 (2005)].

VIII. CONCLUSION

The subject device, QuickRad, and the predicate device, DeepTek (K222781), have similar indications for use, technological characteristics, and principles of operation. After a careful evaluation of the technological features and non-clinical performance testing, it is evident that QuickRad is as safe and effective as DeepTek. Furthermore, QuickRad does not introduce any new concerns related to safety or effectiveness. Hence, QuickRad is considered substantially equivalent to DeepTek.