eRAD, Inc.
Jaye Marotta
Q & R Leader
201 Brookfield Parkway
Suite 160
Greenville, South Carolina 29607

October 31, 2024

Re: K241223
Trade/Device Name: eRAD PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management mnd processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 17, 2024
Received: September 23, 2024

Dear Jaye Marotta:

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, 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

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)*

K241223

Device Name

eRAD PACS

Indications for Use *(Describe)*

eRAD PACS is a software-only medical device used to receive medical images, scheduling information and clinical reports, organize and store them in an internal format, and make the information available across a network via web and customized user interfaces.

eRAD PACS includes software intended for use by qualified professionals for the presentation, review and comparison of diagnostic medical images.

eRAD PACS is for hospitals, imaging centers, reading practices, radiologists, technicians, physicians and other users who require and are granted access to patient image, exam and report information.

The eRAD PACS viewer displays images from DICOM compliant modalities and other devices including CT, computed and digital radiography, MRI, mammography, nuclear medicine, PET, secondary capture, ultrasound, x-ray angiography, x-ray fluoroscopy and visible light systems.

Lossy compressed images and digitized film images must not be used for primary diagnosis of mammography studies. When displaying mammography images for clinical interpretation, only monitors having regulatory clearance for mammography interpretation should be used.

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.

510(k) Executive Summary

Submitter: eRAD, Inc.
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Date Prepared: 04.25.2024

Classification Name: System, Image Processing, Radiological

Common Name: MIMPS, PACS

Proprietary Name: eRAD PACS

Predicate Devices: eRAD PACS, #K120995 (December 3, 2012)

Device Description:

eRAD PACS is a software-only medical image management and processing system, comprised of a central systems manager component, diagnostic viewing components, and an archiving component.

The system is used for patients who undergo an imaging procedure deemed necessary by the patient's physician.

The data flow is as follows:

- Patient and procedure information is optionally acquired by the central system manager to prepare for the acquisition of image objects.
- Image objects are acquired from the image sources, such as imaging modalities, PACS, data archives, and other devices.
- After receiving the procedure information or the image objects, the central system manager searches for and retrieves relevant prior procedure data from the archiving component.

- When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information from a workstation by selecting the item from the operator's worklist.
- The image data is transmitted to and rendered on the user's workstation using the diagnostic viewing components.
- After reviewing the images in the diagnostic viewer, the user optionally creates a clinical report using a text editor or a commercially available speech recognition solution.
- Once the central system manager registers a report, the report is available for access by the referring physician, or it can be exported into a third-party information system.
- At some configured point in time, the image data and the report information are delivered to the archiving component for backup and long-term storage.

Intended Use:

eRAD PACS is a software-only medical device used to receive medical images, scheduling information and clinical reports, organize and store them in an internal format, and make the information available across a network via web and customized user interfaces.

eRAD PACS includes software intended for use by qualified professionals for the presentation, review and comparison of diagnostic medical images.

eRAD PACS is for hospitals, imaging centers, reading practices, radiologists, technicians, physicians and other users who require and are granted access to patient image, exam and report information.

The eRAD PACS viewer displays images from DICOM compliant modalities and other devices including CT, computed and digital radiography, MRI, mammography, nuclear medicine, PET, secondary capture, ultrasound, x-ray angiography, x-ray fluoroscopy and visible light systems.

Lossy compressed images and digitized film images must not be used for primary diagnosis of mammography studies. When displaying mammography images for clinical interpretation, only monitors having regulatory clearance for mammography interpretation should be used.

Substantial Equivalence:

The modifications to the eRAD PACS software device do not alter the fundamental scientific technology of the device. The modification made to the predicate device is a restructure of the internal components for deployment in a cloud environment.

Discussion of Non-Clinical Testing Performed:

Thorough non-clinical system verification and validation testing was conducted in accordance with applicable standards and internal design procedures to verify that the eRAD PACS software product meets user needs and its intended use. Testing demonstrated that the eRAD PACS software product is substantially equivalent to the predicate device.

Conclusions:

The information provided in this premarket notification submission has shown that the eRAD PACS software product is substantially equivalent to the predicate device and is as safe and effective as the predicate for its intended use.