August 19, 2022

Radisen Co., Ltd.
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. , Suite 610
HOUSTON TX 77054

Re: K213520
Trade/Device Name: AXIR-CX
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 20, 2022
Received: July 20, 2022

Dear Dave Kim:

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 (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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

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

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

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213520

Device Name
AXIR-CX

Indications for Use *(Describe)*
AXIR-CX is a software package used with general purpose computing hardware to receive, store, distribute and display chest X-ray images and associated data for patient diagnosis.
AXIR-CX is a software application that enable the DICOM-compliant chest X-ray image [14 x 17 or 17 x 17 inch size] from DR and CR, and after image displaying the user adds the annotation regarding the diagnosis and print out the patient information or send to another PACS system. AXIR-CX is intended to be used by trained medical professionals including physicians, radiologists, and medical technicians. This device is not indicated for use in mammography.

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.

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1. Traditional 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date 510K summary prepared: August 18, 2022

Submitter's Name:	Radisen Co., Ltd.
Submitter's Address:	B-602, Hifield Building, 66, Beolmal-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea, 14058
Submitter's Telephone:	Tel:+82-31-8084-9762
Contact person:	Mr. John Lim / EVP of DR Business Unit
Official Correspondent:	Dave Kim (davekim@mtech-inc.net)
Address:	7505 Fannin St. Ste 610, Houston, TX 77054
Telephone:	+713-467-2607

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	AXIR-CX
Regulation Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Regulatory Class:	II
Product Code:	LLZ

Predicate Device	
Manufacturer:	JPI Healthcare Co., Ltd
Device:	ExamVue PACS
510(k) Number:	K162868
Classification Name:	Imaging Processing System, Radiological
Common Name:	Picture Archiving and Communication System (PACS)
Regulatory Number:	21 CFR 892. 2050
Regulatory Class:	II
Product Code:	LLZ

2. Device Description

The AXIR software is designed for use by radiologists and radiology technicians for annotation in the Chest X-ray images. The AXIR software is developed to use Radisen Flat Panel DR Detector and Radisen Image Viewer. The purpose of AXIR software is for the doctor to annotate Chest X-ray images and then to print out with patient information or sent to another PACS system.

A client user needs to install AXIR-CX first in the recommended PC environment. After installation, the client user chooses a DICOM format in the uploaded patient list to be annotated, and then annotation is written by user after reviewing of image chosen. After annotation has completed it can be printed out, saved or sent to another PACS system.

3. Indications for Use

AXIR-CX is a software package used with general purpose computing hardware to receive, store, distribute and display chest X-ray images and associated data for patient diagnosis.
AXIR-CX is a software application that enable the DICOM-compliant chest X-ray image [14 x 17 or 17 x 17 inch size] from DR and CR, and after image displaying the user adds the annotation regarding the diagnosis and print out the patient information or send to another PACS system. AXIR-CX is intended to be used by trained medical professionals including physicians, radiologists, and medical technicians. This device is not indicated for use in mammography.

4. Summary of Design Control Risk management

After the analysis of risk management, there are no more risk factors and no more actions neede deither. Risk management, during the life cycle from product planning, design process to follow-up management, identified foreseeable risks in accordance with EN ISO 14971:2012, EN 62304:2006+AC:2008, EN 62366:2008 and EN ISO 13485:2016/AC2016 standards.
The validation of risk management was performed by the radiologist who had the experience in clinical field according to the risk management plan. Each item of the validation was checked, and the system had no risks.

5. Comparison with predicate device:

Radisen Co., Ltd, believes that AXIR-CX is substantially equivalent to the predicate device, ExamVue PACS.
Both the subject and predicate devices have the same basic structure (a central server database and associated viewers), function (the storage, display of DICOM images) and follow the DICOM protocol. They have similar intended uses and provide similar suites of tools to fulfil their function.

AXIR-CX differs from the predicate device is user interface and compatible operating system. We believe this does not represent a substantial difference between the two devices, as the change in system requirements reflect the change in computer technology since the release of the predicate device, and the user interface presents the same essential data and supports similar workflow as the predicate device.

6. Substantial Equivalence

Characteristic	Proposed AXIR-CX	Predicate Device ExamVue PACS	Remark
Manufacturer	Radisen Co., Ltd	JPI Healthcare Co., Ltd	
510(k) number	K213520	K162868	
Intended Use	AXIR-CX is a software application that enable the DICOM-compliant chest X-ray image [14 x 17 or 17 x 17 inch size] from DR and CR, and after image displaying the user adds the annotation regarding the diagnosis and print out the patient information or send to another PACS system. AXIR-CX is intended to be used by trained medical professionals including physicians, radiologists, and medical technicians. This device is not indicated for use in mammography.	ExamVue PACS is an image management system intended to be used by trained professionals, including physicians, radiologists, nurses and medical technicians. The software is a software package used with general purpose computing hardware to receive, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage. This device is not indicated for use in mammography. ExamVue PACS supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CR and DX.	Similarity
Performance Standard	21 CFR 892.2050	21 CFR 892.2050	Same
Operating System Requirement	Window 10 and Window based operating system	Window 7 or Window 8 or Window 10	Similarity
Imaging Archive	Yes (DICOM 3.0 Standard)	Yes (DICOM 3.0 Standard)	Same
Image display	Yes	Yes	Same
Patient Search	Yes	Yes	Same
Distance and Angle Measurement	No	Yes	Difference
Window Level Adjustment	No	Yes	Difference

Zoom and Magnify Function	No	Yes	Difference
Line Profile and Histogram	No	Yes	Difference
DICOM Directory Reading	Yes	Yes	Same
DICOM Query/Retrieve	Yes	Yes	Same
DICOM Import	No	Yes	Same
DICOM CD burn	No	Yes	Difference
Annotation	Yes	Yes	Same
DICOM Print	Yes	Yes	Same
DICOM Tag Display	No	Yes	Difference
Patient Information Editing	No	Yes	Difference

There is no significant difference between AXIR-CX and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function and operational principles and intended use.

7. Safety, EMC and Performance Data

Safety testing and documentation was performed in accordance with IEEE 1012-2012, Standard for System and Software Verification and Validation. [AXIR-CX-SVR]

8. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Radisen Co., Ltd, concludes that AXIR-CX is safe and effective and substantially equivalent to predicate device as described herein.