August 6, 2025

Shen Zhen Cambridge-hit Co., Ltd.
℅ Fu Field
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue
Xili Town, Nanshan District
Shenzhen, GD 518000
China

Re: K251038
Trade/Device Name: Digital Radiographic Imaging Acquisition Software - DR (RiasDR)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 7, 2025
Received: July 7, 2025

Dear Fu Field:

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.

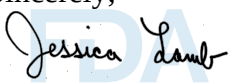
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier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

K251038

Device Name

Digital Radiographic Imaging Acquisition Software - DR (RiasDR)

Indications for Use *(Describe)*

The RiaspDR software directly controls and acquires general radiographic images of human anatomy (excluding fluoroscopic, angiographic, dental and mammographic applications). The RiaspDR software is designed to work with X-ray images from the Mars1417X detector (K210316).

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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510(k) Summary

1. Contact Details

1.1 Applicant information

Applicant Name	Shen Zhen Cambridge-hit Co., Ltd.
Address	1st Floor, Building A1, Hualianfeng Building, Huaning Road,Dalang Street, Longhua District, Guangdong Province, China.
Phone No.	+86(755)23226094
Contact person	Ming Zhao
Date Prepared	Apr. 7, 2025
E-mail	ming.zhao@iraygroup.com

1.2 Proposed device manufacturer

Applicant Name	iRay Group
Address	No. 999, Huanqiao Road, Pudong New Area 201315, Shanghai, China.

1.3 Submission Correspondent

卓远天成	Shenzhen Joyantech Consulting Co., Ltd 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518000, China
Phone No.	+86-755-86069197
Contact person	Field Fu
Contact person's e-mail	field@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Digital Radiographic Imaging Acquisition Software Platform – DR (RIASPDR)
Model	Not applicable
Classification	II
Classification name	Radiology
Product code	LLZ
Regulation No.	892.2050

3. Legally Marketed Predicate Device

Trade Name	Econsole1
510(k) Number	K152172

Product Code	LLZ
Manufacturer	DRTECH Corporation

4. Device Description

RIASPDR is Radiographic Imaging Acquisition Software Platform. RIASPDR software directly controls and acquires images from Mars1417X detector(K210316) whose manufacturer is iRay Technology. Furthermore, RIASPDR acquires and processes images. In addition, it complies with DICOM standards and is able to transmit and receive data with the PACS system.

5. Device specification

The deviation of the length measurement should not exceed 5%; The deviation of the area measurement should not exceed 10%; The deviation of the perimeter measurement should not exceed 5%; The deviation of the angle indication value from the actual value should be within ±0.5°.

6. Intended Use/Indication for Use

The RiaspDR software directly controls and acquires general radiographic images of human anatomy (excluding fluoroscopic, angiographic, dental and mammographic applications). The RiaspDR software is designed to work with X-ray images from the Mars1417X detector (K210316).

7. Substantial Equivalence Comparison

Item	Subject Device	Predicate Device: (K152172)	Comments
Regulation number	892.2050	892.2050	Same
Classification	Ⅱ	Ⅱ	Same
Product Code	LLZ	LLZ	Same
Intended use/Indications for use	The RiaspDR software directly controls and acquires general radiographic images of human anatomy (excluding fluoroscopic, angiographic, dental and mammographic applications). The RiaspDR software is designed to work with X-ray images from the Mars1417X detector	The Econsole1 software is indicated for use in general radiographic images of human anatomy (excluding fluoroscopic, angiographic, and mammographic applications).	Same

Item	Subject Device	Predicate Device: (K152172)	Comments
	(K210316).		
Acquisition devices	Digital X-ray Detector	Digital X-ray Detector	Same
Software Function	Image viewing; Image search; Image storage; Image annotation; Image measurement; Image processing;	Image viewing; Image search; Image storage; Image annotation; Image measurement; Image processing; Image stitch	Same
DICOM 3.0 Compatibility	Yes	Yes	Same
Wireless function	Yes, by TCP/IP or WIFI. The software interacts with the Flat Panel Detector (FPD, that is, Digital X-ray Detector) by calling the driver provided by the manufacturer of the FPD. The data interaction between the FPD and the software can be wired or wireless, depending on the Design of the FPD.	No	Different (note)

8. Non-clinical Testing

As required by FDA Guidance, Software verification and validation testing were conducted and documentation was provided in this 510(k). Results demonstrated that the predetermined acceptance criteria were met.

Software Verification and Validation Testing was performed in accordance with internal requirements, international standards and guidance shown below, the safety and effectiveness of RIASPDR were supported, and the substantial equivalence to the predicate device was demonstrated:

--- Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023.

---Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, issued on September 27, 2023.

---Digital Imaging and Communications in Medicine (DICOM) Set.

9. Clinical testing

Not applicable.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to legally marketed predicate devices (K152172).