June 15, 2026

Jpi Healthcare Co, Ltd.
% Jeong DoAn
Regulatory affairs Manager
Woolim E-Biz Center 608-Ho,28, Digital-Ro 33gil, Guro-Gu
SEOUL, 08377
REPUBLIC OF KOREA

Re: K260482
Trade/Device Name: DRE Duo
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: May 11, 2026
Received: May 11, 2026

Dear Jeong Doan:

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,

for

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems 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)*
K260482

Device Name
DRE Duo

Indications for Use *(Describe)*
The DRE Duo is intended for use in hospitals and clinical settings under the supervision of qualified medical professionals.The system is intended to generate X-ray radiation for general radiographic examinations of the human body. The system is designed to be used in conjunction with external image receptors, such as film-based radiography systems or compatible digital detectors, which are not part of the system.

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.

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JPI Healthcare

DRE Duo

510(k) Summary

1. Submission

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Contact: Do An Jeong

Website: http://www.jpi.co.kr/

Submission number : K260482

2. Correspondent

Name : JPI Healthcare Solutions, Inc

Address : 3555 Veterans Memorial Highway Unit D Ronkonkoma NY 11779

United States

Telephone : 516-513-1330-101

Contact : Jorge Solano

Email : Jorge.solano @jpihealthcare.com

3. Date Prepared

05/11/2026

4. Device identification

Product Name: DRE Duo

Model Name:

DRE Duo Model	JPI-DRED-DCN/01	JPI-DRED-ECN/01	JPI-DRED-BDN/01	JPI-DRED-BGN/01
Generator Model	PSG-HR40		PSG-HR50	VZW2556 RB2
Generator Output Power	40kW		50kW	
X-ray Tube Model	E7239X	E7242X	E7252X	

Common Name: Diagnostic X-ray system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: KPR

5. Predicate Device

Product Name : GXR-Series Diagnostic X-Ray System
510(k) Number : K192364
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: KPR

6. Device description

The DRE Duo is a Diagnostic X-ray system intended for use in general radiographic examinations of the human body.
It is designed to be used in conjunction with compatible X-ray detectors or film/screen cassettes, serving as a replacement for conventional film- or screen-based radiography systems in general diagnostic procedures.
The DRE Duo interfaces with an X-ray generator to support appropriate control of exposure and dose in accordance with clinical protocols. The system is intended for use in hospital or clinical environments under the supervision of licensed medical practitioners or qualified radiologic technologists

7. Indications for use

The DRE Duo is intended for use in hospitals and clinical settings under the supervision of qualified medical professionals.
The system is intended to generate X-ray radiation for general radiographic examinations of the human body. The system is designed to be used in conjunction with external image receptors, such as film-based radiography systems or compatible digital detectors, which are not part of the system.

8. Substantial equivalence

8.1 General Information

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Device Name	DRE Duo	GXR-S(GXR-52)	GXR-S(GXR-40)	Not applicable
Predicate Family	N/A	GXR-Series Diagnostic X-Ray System (K192364)	Same family	Not applicable
Manufacturer	JPI Healthcare Co., Ltd.	DRGEM Corporation	DRGEM Corporation	Administrative difference only
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same	Same
Regulation Name	Stationary X-ray System	Stationary X-ray System	Same	Same
Product Code	KPR	KPR	Same	Same
Regulatory Class	II	II	Same	Same
Device Type	Diagnostic X-ray system	Diagnostic X-ray system	Same	Same

8.2 Intended Use and Use Environment

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Intended Use / Indications for Use	The DRE Duo is intended for use in hospitals and clinical settings under the supervision of qualified medical professionals. The system is intended to generate X-ray radiation for general radiographic examinations of the human body. The system is designed to be used in conjunction with external image receptors, such as film-based radiography systems or compatible digital detectors, which	Stationary diagnostic X-ray imaging system for acquiring X-ray images of desired parts of a patient's anatomy.	Same general family intended use	Same intended use; wording difference only

	are not part of the system.			
Intended Users	Qualified medical professionals	Qualified medical professionals	Same	Same
Use Environment	Hospitals, clinics, imaging centers, and healthcare facilities	Hospitals, clinics, imaging centers, and healthcare facilities	Same	Same

8.3 Fundamental Scientific Technology

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Fundamental Technology	Stationary radiographic X-ray system using an X-ray generator, X-ray tube, collimator, patient positioning/support components, and external image receptor	Stationary radiographic X-ray system using an X-ray generator, X-ray tube, collimator, patient positioning/support components, and external image receptor-based imaging workflow	Same fundamental technology	Same fundamental technology
Generator Type	High-frequency X-ray generator	High-frequency X-ray generator	Same	Same
Radiography Mode	Radiography mode	Radiography mode	Same	Same

8.4 System Configuration

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Principal Components	X-ray tube, generator, collimator, tube stand, wall bucky stand, patient table, control console	X-ray tube, generator, collimator, tube stand, wall bucky stand, patient table, control console	Same family architecture	Same principal system architecture
Patient Support Components	Bucky table / patient table, wall bucky stand, tube stand	PBT series tables, WBS series wall bucky stand, TS series tube stand	Other table/support options within family	Mechanical configuration difference only
Console / Controller	Console-based system control	Membrane console / touch console / interface module as applicable	Same family concept	Engineering configuration difference only

8.5 Generator Characteristics

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Generator Model	VZW2556RB2, PSG-HR40, PSG-HR50	GXR-52	GXR-40	Engineering/configuration difference only
Output Class	40 kW / 50 kW	52 kW	40 kW	Minor variation only
Line Power / Phase	220–240 VAC, 50/60 Hz, 1Ø; 380/400/480 VAC, 50/60 Hz, 3Ø	380/400/480 VAC, 50/60 Hz, 3Ø	220–230 VAC, 50/60 Hz, 1Ø or 380/400/480 VAC, 50/60 Hz, 3Ø	Minor variation only
kV Range	40–150 kV	40–150 kV	40–125 kV (optional 150 kV)	Minor variation only
mA Range	10 to 500 / 630 mA depending on model	10 to 640 mA	10 to 500 mA	Minor variation only
Timer Range	0.001 to 6.3 sec / 10 sec, depending on model	0.001 to 10 sec	0.001 to 10 sec	Minor variation only
mAs Range	0.1 to 320 mAs / 0.4 to 630 mAs, depending on model	0.1 to 500 mAs (optional to 1,000 mAs)	0.1 to 500 mAs	Minor variation only

8.6 X-ray Tube Characteristics

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Tube Model	CANON E7239X, CANON E7242X, CANON E7252X	CANON E7252X	CANON E7239X, CANON E7242X	Same
Focal Spot Size	1.0/2.0 mm, 0.6/1.5 mm, 0.6/1.2 mm	0.6/1.2 mm	1.0/2.0 mm, 0.6/1.5 mm	Same
Maximum kV	125 kV / 150 kV	150 kV	125 kV	Same
Anode Angle	16°, 14°, 12°	12°	16°, 14°	Same
Inherent Filtration	0.9 mmAl/75 kV	0.9 mmAl/75 kV	0.9 mmAl/75 kV	Same
Heat Capacity	140 kHU, 200 kHU, 300 kHU	300 kHU	140 kHU, 200 kHU	Same

8.7 Collimator Characteristics

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Collimator Model	CRUX FR04, CRUX FR10	DXC-RML, R302MLP/A#	R108, DXC-RML	Engineering/configuration difference only
Field Shape	Square X-ray field	Square X-ray field	Square X-ray field	Same
Maximum Field	43.5 × 43.5 cm /	44 × 44 cm /	43 × 43 cm /	Minor variation only

Size	43 × 43 cm	48 × 48 cm	44 × 44 cm	
Maximum kV	150 kV	150 kV	150 kV	Same
Inherent Filtration	1.0 mm Al / 75 kV	Min. 2.0 mm Al eq. at 75 kV	Min. 2.0 mm Al eq. at 75 kV	Engineering/configuration difference only
Additional Filtration (Final production configuration)	1.0 mm Al	Not separately specified in this summary	Not separately specified in this summary	Clarification of subject device configuration only
Total Filtration (Final production configuration)	2.9 mm Al equivalent	Not separately specified in this summary	Not separately specified in this summary	Difference dose not raise new questions of safety or effectiveness
Light Source	LED Lamp	LED Lamp	LED Lamp	Same

Note: The filtration values listed for the subject device in Sections 8.6 and 8.7 represent component-level inherent filtration only and do not by themselves represent the total system filtration. The X-ray tube provides 0.9 mm Al inherent filtration and the collimator provides 1.0 mm Al inherent filtration, resulting in 1.9 mm Al of component inherent filtration. In addition, the final production configuration of the subject device includes an additional 1.0 mm Al filter. Accordingly, the total filtration of the subject device is 2.9 mm Al equivalent. Performance testing was conducted using the final production configuration with total filtration of 2.9 mm Al equivalent.

8.8 Patient Table / Support Structure

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Patient Support / Table Configuration	4-way or 6-way bucky table depending on configuration	PBT series patient table depending on configuration	Other family table options	Mechanical design difference only

8.9 Standards and Compliance

Item	Subject Device	Primary Predicate Device	Supporting Predicate Configurations	Impact of Differences
Electrical Safety	IEC 60601-1, IEC 60601-1-2	Same device category standards	Same	Same
Radiation Safety	IEC 60601-1-3, IEC 60601-2-54	Same device category standards	Same	Same
Human Factors	IEC 62366 / IEC 60601-1-6, as applicable	Same device category standards	Same	Same
Risk Management	ISO 14971	Same device category expectations	Same	Same
Quality System	ISO 13485	Same device category expectations	Same	Same

Software	FDA Guidance: Content of Premarket Submissions for Device Software Functions (June 2023)	Same device category expectations	Same	Same
Cyber Security	**Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions** *Guidance for Industry and Food and Drug Administration Staff* **February 2026**	Same device category expectations	Same	Same

9. Performance Validation Supporting Substantial Equivalence

Substantial equivalence is supported not only by comparison of intended use and technological characteristics, but also by performance validation demonstrating that the subject device performs safely and effectively for its intended use.

The subject device performance validation included, as applicable:

- Electrical safety testing
- Electromagnetic compatibility testing
- Radiation safety / essential performance testing
- Radiation output reproducibility
- Radiation output linearity
- Accuracy of kV, mA, exposure time, and mAs
- Mechanical and functional verification
- Risk management verification of relevant risk control measures

Image quality performance testing was conducted with a compatible flat panel detector integrated with the system under defined exposure conditions and standardized methods.

Performance validation was conducted using the final production configuration of the DRE Duo system, including total filtration of 2.9 mm Al equivalent.

The testing included objective image quality metrics such as MTF and DQE.

The results demonstrate that the subject device performs as intended and that any differences from the predicate device do not raise new questions of safety or effectiveness.

10. Non-clinical test summary

No clinical testing was conducted for the DRE Duo Diagnostic X-ray System.

Clinical data were not required to support this submission because the device has a well-established intended use, operating principle, and technological characteristics.

The safety and effectiveness of such devices have been demonstrated through non-clinical performance testing, recognized standards, and comparison with legally marketed predicate devices under product code KPR.

No new questions of safety or effectiveness are raised

11. Summary

Based on the performance data as documented in the above testing, the DRE Duo with Radiography is found to have a safety and effectiveness profile that is similar to the predicate device.