September 19, 2023

DRGEM Corporation
℅ Mr. Park Sunghee
Quality Management Director
7F/13F, E-B/D Gwangmyeong Techno-Park, 60Haan-ro
Gwang-Myeong-si, Gyeong-gi-do 14322
KOREA

Re: K232178
Trade/Device Name: GXR-ES/ECS Diagnostic X-Ray System,
(Models GXR-ES series, GXR-ECS series)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: July 24, 2023
Received: July 24, 2023

Dear Mr. Sunghee:

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); 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,

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)*
K232178

Device Name
GXR-ES/ECS Diagnostic X-ray System, (Models : GXR-ES series, GXR-ECS series)

Indications for Use *(Describe)*

The "GXR-ES/ECS" System is intended for use in generating radiographic images of human anatomy. The Diagnostic X-ray System consisting of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, patient table, wall Bucky stand, and a tube, operates on a high-frequency inverter method, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems. Such as the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position

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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510(k) Summary

K232178

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER [21 CFR 807.92(a) (1)]

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Contact Person: Mr.Sung-Hee PARK, Director | Quality

Management Date Prepared: May 25, 2023

II. PROPOSED DEVICE INFORMATION [21 CFR 807.92(a) (2)]

Product Name: GXR-ES/ECS Diagnostic X-Ray System, (Models GXR-ES series, GXR-ECS series)
Common Name: Stationary X-Ray System
Classification Name: Stationary x-ray system
Product Code: KPR
Regulatory Class: II
Regulation Number: 892.1680

III. PREDICATE DEVICES INFORMATION [21 CFR 807.92(a) (3)]

Product Name: GXR-series Diagnostic X-Ray System, (Models GXR-S series)
Common Name: Stationary X-Ray System
Classification Name: Stationary x-ray system
510(k) Number : K202572
Product Code: KPR
Regulatory Class: II
Regulation Number: 892.1680

IV. DEVICE DESCRIPTION [21 CFR 807.92(a) (4)]

Device Features:

The GXR-ES/ECS system offers stable operation and good performance, delivering state-of-the-art image quality with good quality images.

This diagnostic x-ray system is designed to diagnose human body by providing radiographic x-ray image with anatomical structure.

The flat-panel detectors (a necessary component of a fully-functional diagnostic x-ray system) are not part of the subject device.

"GXR-ES/ECS" System provides good performance and stable operation while providing good quality images.

The operator control console is designed in two types to be simple and user-friendly.

The first type features a large graphic LCD panel display and a soft membrane switch to allow easy selection or change of X-ray parameters.

The second type can be easily operated using the Touch function through a large graphic LCD panel display and intuitive GUI configuration.

The "GXR-E/EC" Series high frequency X-ray generator features excellent accuracy, reproducibility and long-term stability with UPS functionality.

The APR (Anatomical Programming) and the optional AEC (Automatic Exposure Control) features give you controlled exposure factors, automatically optimized for the radiological study selected. Automatic Calibration function of the generator will minimize calibration time and set correct calibration value.
Also the control console of "GXR-ES/ECS" System offers graphic waveform and data of x-ray exposure.
So, it is not needed to perform the manual calibration procedure with measurement equipment.
Naturally, the generator supports Automatic, Semi-auto and Manual Calibration functions.

Remote Diagnosis Software can make report about information of system, user, service and error by the USB connection between PC and control console, and transfer report to manufacturer via internet. So this function enables fast and accurate diagnosis on problems and saves service cost and system downtime.

The control console allows the operator to select the technique factors, image receptors, etc., and to initiate an X-ray exposure.

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- Compact System for essential uses.
- Good Performance and Stability.
- Real-time monitoring self-diagnosis function and Error code display.
- Overload & HU protection and error message display.
- Automatic calibration without measurement equipment.
- Adaptable calibration keeps up accuracy through long-term usage.
- The system is small, light and features a convenient modular design and user-friendly system configuration.
- Constant dose output due to kV and mA regulation during exposures.
- Large graphic LCD panel user-friendly controls for APR and technique display at a glance.
- Time and mA / mAs selections are based on R'10 rule of ISO 497.
- Remote diagnosis software for system diagnosis via internet.
- Easy parameter setting and Firmware upgrade.
- System diagnosis, Error log and Statistical data display.

· **Device Identification:**

The subject device consists of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, a patient table, wall Bucky stand, and an x-ray tube, that operates on a high-frequency inverter method.

· **Device Characteristics:**

Software

The subject device ‘GXR-ES/ECS Diagnostic X-ray System’ use software (firmware).

Its S/W can perform system control such as the collimation size, filter selection, Control of Generator.

The software being used is identical to the predicate device “GXR-S series Diagnostic X-ray System”, and its LOC (Level of Concern) is 'Moderate'.

Accordingly, this software (X-CON) is based on predicate device ‘GXR-S series Diagnostic system.

Determination

(Moderate Level of Concern)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets all images and information being displayed and printed.

· **Environment of Use:**

This “GXR-ES/ECS” System is for use by medical professional Facility.
To prevent excess radiation exposure to patient and operator from either primary or secondary radiation, this “GXR-ES/ECS” System must be operated and serviced by trained personnel who are familiar with the safety precautions required.

· **Brief Written Description of the Device:**

The operating principles are as follows.
The irradiation conditions are 40 to 125 (150) kVp at the photographing site, and the tube current is 10 to 400 (500) mA. When X-rays generated under X-ray irradiation conditions enter the X-ray Film, the film detects X-rays incident through the incident surface during X-ray irradiation, and finally generates a radiographic image when X-ray irradiation is completed.

· **Material of Use:**

The “GXR-E/EC series Diagnostic X-ray System has a two patient-applied part.

Some device components may briefly touch the patient. Device biocompatibility has been tested according to relevant standards and it was found that critical components satisfy biocompatibility requirements as applicable to the device Indications for Use.

· **Compatible x-ray image detector:**

This model is an analog-based X-ray system and does not include image detectors as an essential component. It is possible to compatible with available detectors and can be used with certified detector panel sizes as long as they fit.

• Available detector
- Size (inch): 17X17, 17X14, 10 X12
- Products whose compatibility has been verified by the manufacturer can be used.

V. INDICATION FOR USE [21 CFR 807.92(a) (5)]

"GXR-ES/ECS" System is indicated for use in generating radiographic images of human anatomy. The Diagnostic X-ray System consisting of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, patient table, wall Bucky stand, and a tube, operates on a high-frequency inverter method, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems. Such as the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position

VI. TECHNOLOGICAL CHARACTERISTICS [21 CFR 807.92(a) (6)]

The subject device and the primary predicate device are stationary x-ray devices. There will be 2 main differences:

First, this device, 'GXR-ES/ECS Diagnostic X-ray System has Compact System', is for only essential use in that it is composed of simplified mechanical parts.

But, the predicate device 'GXR- series Diagnostic Imaging System' has Manual type as well as motorized option of Tube stand, patient table and WBS (Diagnostic X-ray Full system). And the subject device has lower high voltage output rating than predicate device for Use of small-scale hospital facility operation.

Second, Difference between subject and predicate device is diversity of the power supply method of the generator

Generally, the subject device 'GXR-ES, ECS' has general and capacitor type generator supplied from wall power. However, the predicate device 'GXR-series Diagnostic Imaging System' has also UPS battery type (total three type).

Differences between the subject device and the predicates has no impact on safety or effectiveness of the new device and does not raise any new potential or increased safety risks and is equivalent in performance to existing legally marketed devices.

VII.SUBSTANTIAL EQUIVALENCE [21 CFR 807.92(b)]

Item	Subject Device	Predicate Device	Impact of Differences
Device Name	GXR-ES/ECS Series Diagnostic X-ray System	GXR-Series Diagnostic X-Ray System (K202572)	Not applicable
Manufacturer	DRGEM Corporation	DRGEM Corporation	Not applicable
Model Number	GXR-ES series, GXR-ECS series	GXR-S series	Not applicable
High Frequency X- ray Generator			
Output Power	20kW, 25kW, 32kW, 40kW, 50kW	32KW, 40KW, 52KW, 68KW, 82KW	Yes, there is a difference in output values but no difference in generators. See Difference Explanation below.
Generator models (manufactured by DRGEM)	GXR-E20, GXR-E25, GXR-E32, GXR-E40, GXR-E50	GXR-32, GXR- 40, GXR-52, GXR-68, GXR- 82	Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference.
Line voltage	100~120VAC 200~240VAC	220~230VAC, 380/400/480VA C,	Yes, there are differences in line voltage depending upon the system requirements. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference
Image Acquisition System			

Flat panel Detector	Detector is not supplied with system	Detector is not supplied with system	Not applicable
Patient table			
Configuration model	PBT-E	PBT-4, PBT-6, PDT-1	Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
Movement	Longitudinal : 1050mm ± 10mm	Longitudinal : 1000mm ± 500mm	
Wall Bucky stand			
Configuration model	WBS-E, WBS	WBS, WBS-TM	Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
Dimension/weight	560(W) x 690(D) x 1,826(H)mm / 32.4kg(71.4lbs) (Floor Base) 420(W) x 256(D) x 1,826(H)mm / 21.4kg(47.2lbs) (Floor-Wall Mounted) 659(W) x 393(D) x 2,169(H)mm / 120kg(264lbs)	659(W) x 445(D) x 1,599(H)mm / 110kg(242lbs) 659(W) x 445(D) x 1,749(H)mm / 113kg(249lbs) 659(W) x 445(D) x 1,919(H)mm / 116kg(255lbs) 659(W) x 445(D) x 2,169(H)mm / 120kg(264lbs)	
Tube stand			
Configuration model	TS-FT6, TS-FT4	TS-FC6, TS-FC4, TS-FC2 TS-FM6, TS-CSA, TS-CSE	Not applicable
Tube Rotation Angle	±135°	±135°	
X-ray tube			

Configuration model	DXR-8M, DXT-10M, DXT-11M, DXR-12M, E7239X, E7242X, E7884X,	E7239X, DXT-8M, E7242X, DXT-11M E7843X, DXT-10M E7876X, DXT-12M E7884X, E7252X DXT-14U, RAD-14U, DXT-15U, RAD-21 RAD-60, E7255FX, E4254FX	No Impact of difference
Max. kV	125kV, 150kV	125kV, 150kV	
Collimator			
Configuration model	DXC-RML	DXC-RML, DXC-RMH MCR, R108, R302A, R302MLP/A, R302MFMLP/A	Yes, there is a difference. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
Lamp Type	LED lamp (Over 160LUX at 100cm SID)	LED and Halogen lamp (Over 160LUX at 100cm SID)	

VIII. SUMMARY OF NON-CLINICAL Data [21 CFR 807.92(b) (1)]

Nonclinical Testing:
The GXR-ES/ ECS Series Diagnostic X-Ray System, has been assessed and tested and has passed predetermined testing criteria. The Validation Test Plan was designed to evaluate input functions, output functions, and actions performed by the subject device and followed the process documented in the System Validation Test Plan.

Nonclinical testing results are provided in the 510(k). Validation testing indicated that as required by the risk analysis, designated individuals performed all verification and validation activities and that the results demonstrated that the predetermined acceptance criteria were met.

Std #	Safety/EMC Standards Description	FDA Rec. Standard #
IEC 60601-1-3	Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	12-269
IEC 60601-1-6	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 60601-2-28	IEC 60601-2-28 Medical electrical equipment Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	12-309
IEC 60601-2-54	IEC 60601-2-54 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	12-317
IEC 60601-1-2 (EMC)	IEC 60601-1-2 Edition 4.0 2014-02. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances Requirements and tests.	19-8
IEC 62304:2006	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	13-79
IEC 60601-1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-4
ISO 14971:2019	ISO 14971:2019 Third Edition, Medical devices - Applications of risk management to medical devices.	5-125
ISO 15223-1	ISO 15223-1 Fourth Edition 2021-07, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.	5-134
TR 60601-4-2	TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-19
FDA Guidance	Pediatric Information for X-ray Imaging Device Premarket Notifications dated November 28, 2017	
FDA Guidance	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014	
FDA Guidance	Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005	

Summary:

Based on the performance as documented in the V&V Testing, the subject device was found to have a safe and effectiveness profile that is similar to the predicate device.

The above standards were used to develop and verify electrical safety, and EMC. GXR-ES/ ECS Series Diagnostic X-Ray System device has met all the requirements listed in the Standards except for inapplicable requirements.

The subject device conform to all applicable aspects of 21CFR 1020.30

IX. CONCLUSIONS [21 CFR 807.92(b) (3)]

The 510(k) Pre-Market Notification for GXR-ES/ECS series Diagnostic X-ray System, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device and the predicate device are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs comparably to the predicate devices.