DRGEM Corporation
% Mr. Carl Alletto
Consultant
OTech Inc.
8317 Belew Drive
MCKINNEY TX 75071

September 24, 2020

Re: K202572
Trade/Device Name: GXR-Series Diagnostic X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: August 27, 2020
Received: September 4, 2020

Dear Mr. Alletto:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K202572

Device Name
GXR-Series Diagnostic X-Ray System

Indications for Use *(Describe)*

GXR-Series Diagnostic X-Ray System, is a stationary X-ray imaging system, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography or bone density applications.

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 of Safety K202572

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared: September 18, 2020

I. SUBMITTER

DRGEM Corporation
7F E-B/D Gwangmyeong Techno-Park 60, Haan-ro
Gwangmyeong-si, Gyeonggi-do, 14322 Korea
Email: radcheck@drgem.co.kr

Contact Person: Mr. Ki-Nam YANG, Director | QM representative

II. DEVICE

Product Name: GXR-Series Diagnostic X-Ray System
Common Name: Digital Diagnostic X-ray System
Regulation Name: Stationary X-Ray System
Product Code: KPR
Regulation number: 892.1680
Regulatory Class: II

III. PREDICATE DEVICE

Product Name: GXR-Series Diagnostic X-Ray System
Submission Number: K192364
Decision Date: 09/26/2019
Common Name: Digital Diagnostic X-ray System
Regulation Name: Stationary X-Ray System
Product Code: KPR
Regulation Number: 892.1680
Regulatory Class: II

IV. DEVICE DESCRIPTION

GXR Series Diagnostic X-ray System is a digital radiographic system. There are 5 power output configurations which are reflected in the model's designation "GXR-XX" The models have 5 different output power ratings:

DRGEM System Model	**GXR-32SD**	**GXR-40SD**	**GXR-52SD**	**GXR-68SD**	**GXR-82SD**
DRGEM Generator Model	GXR-32	GXR-40	GXR-52	GXR-68	GXR-82
Generator Output Rating	32kW	40kW	52kW	68kW	82kW

The subject device, GXR Series Diagnostic X-ray System, is designed to diagnose the human body by providing radiographic x-ray image with anatomical structure.

The subject device has the same x-ray hardware components and image management software as the predicate device. 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.

The operator control console is designed to be user-friendly, and the user can select or change x-ray parameters easily using a large graphic LCD panel display and a soft membrane switch. The GXR Series high frequency X-ray generator (manufactured by

DRGEM) features accuracy, reproducibility and long-term stability with capacitor assisted general line power supply. The APR (Anatomical Programming) and the optional AEC (Automatic Exposure Control) features gives the user control of exposure factors, automatically optimized for the radiological study selected.

The digital flat panel detectors provide spatial resolution, MTF, DQE and stability based on fine pixel pitch. Selection of an anatomical study on the imaging software automatically sets up the x-ray generator's pre-programmed exposure technique setting and post image processing for selected study. The subject device is able to use a total of 10 different digital detectors, (8 new plus 2 cleared in the predicate, which have been previously cleared by the 510(k) process:

- VAREX, 4343R v3 - K172951(predicate)
- VAREX, 4336W v4- K161459 (predicate)
- VAREX, XRpad2 3025 HWC-M- K161942
- VAREX, XRpad2 4336 HWC-M- K161966
- VAREX, XRpad2 4343 HWC-M- K181526
- i-Ray, Mano4336W- K201004
- i-Ray, Mano4343W- K201043
- Vieworks, VIVIX-S1417N(NAW,NBW)-K163703
- Vieworks, VIVIX-S1717N(NAW,NBW)- K152894
- VAREX, 4343W- K161459

The GXR Series Diagnostic X-ray System consists of a combination of an x-ray generator, and associated equipment such as tube stand, patient table, and, digital imaging system. The main power cabinet contains the HT tank and control circuits, the filament drivers, the low speed starter, and interface connections to the room equipment.

- Tube stand and patient table allows the operator to position the patient.
- Full Featured Imaging Software & Digital Image Processing
- Control console:
  - The control console allows the operator to select the technique factors, image receptors, etc., and to initiate an X-ray exposure.
  - Real-time monitoring self-diagnosis function and Error code display
  - Overload & HU protection and error message display
  - Support programmable max. 1,280 APR conditions with APR utility software
  - Automatic calibration without measurement equipment.
  - Adaptable calibration keeps up accuracy through long-term usage
  - Smaller, lighter and 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

The image management software, RADMAX Digital Imaging Software (K182537) by DRGEM, is used in both the predicate and subject device to serve as a convenient interface to the hardware and images. Anatomical view-based digital image processing automatically optimizes and enhances the quality of the captured images. RADMAX

(K182537) Digital Imaging Software is designed for acquiring images and processing the acquired images. The software can be used together with a digital X-ray detector and or an X-Ray generator. The main features of the RADMAX software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, and image processing. It can also perform system control such as the collimation size, and filter selection. The following are general features.

- Windows based graphic user interface
- Multi-image display (1x1 ~ 4x4)
- Multi-image selection
- Auto display layout changing function
- X-ray generator control panel
- Unlimited procedure step
- Quick step-add feature and image maintenance feature by popup menu
- ROI changing and creation feature
- Marker feature (support the creation of unlimited number of markers by user)
- Multi-language support
- EXCEL sheet for language support (only possible on Microsoft Office automation environment)
- DAP meter (optional)
- Unlimited PACS code (CPT code)
- Default anatomic program more than 700
- Support DICOM Worklist SCU, DICOM Storage SCU and transfer function
- Support DICOM Multi-transfer function
- High-performance post-processing feature
- Copy & Move Images
- Dose monitoring function
- Built-in memory function
- Grid line suppression function
- Reject analysis function

V. INDICATIONS FOR USE

GXR-Series Diagnostic X-Ray System, is a stationary X-ray imaging system, for the purpose of acquiring X-ray images of the desired parts of a patient's anatomy. This device is not intended for mammography or bone density applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Summary of differences:

The subject device can interface to one of eight previously cleared digital flat panel detectors in addition to the 2 detectors used in the predicate device as listed above.

- VAREX, 4343R v3 - K172951(predicate)
- VAREX, 4336W v4- K161459 (predicate)
- VAREX, XRpad2 3025 HWC-M- K161942
- VAREX, XRpad2 4336 HWC-M- K161966
- VAREX, XRpad2 4343 HWC-M- K181526
- i-Ray, Mano4336W- K201004

- i-Ray, Mano4343W- K201043
- Vieworks, VIVIX-S1417N(NAW,NBW)-K163703
- Vieworks, VIVIX-S1717N(NAW,NBW)- K152894
- VAREX, 4343W- K161459

The following information compares the subject device to the predicate.

Any differences between the subject device and the predicated device have no negative impact on safety or efficacy of the subject device and does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Specification	Predicate device K192364	Subject Device	Impact of Differences
Device Name	GXR-Series Diagnostic Imaging System	GXR-Series Diagnostic Imaging System	None
Manufacturer	DRGEM Corporation	DRGEM Corporation	None
Model Number	GXR-SD/CSD/USD	GXR-SD/CSD/USD	None
High Frequency X-ray Generator			
Output Power	32KW, 40KW, 52KW, 68KW, 82KW	32KW, 40KW, 52KW, 68KW, 82KW	None
Generator models (manufactured by DRGEM)	GXR-32, GXR-40, GXR-52, GXR-68, GXR-82 GXR-C32, GXR-C40, GXR-C52	GXR-32, GXR-40, GXR-52, GXR-68, GXR-82 GXR-C32, GXR-C40, GXR-C52	None
Line voltage	220~230VAC 380/400/480VAC	220~230VAC 380/400/480VAC	None
kV Range	40~125kV, 1kV step (Optional 40~150kV)	40~125kV, 1kV step (Optional 40~150kV)	None
mA Range	GXR-32=10 to 400mA GXR-40=10 to 500mA GXR-52=10 to 640mA GXR-68=10 to 800mA GXR-82=10 to 1,000mA	GXR-32=10 to 400mA GXR-40=10 to 500mA GXR-52=10 to 640mA GXR-68=10 to 800mA GXR-82=10 to 1,000mA	None
Image Acquisition			
Detectors	VAREX, 4343R v3 - K172951 VAREX, 4336W v4- K161459	VAREX, 4343R v3 - K172951 VAREX, 4336W v4- K161459 VAREX, XRpad2 3025 HWC-M- K161942 VAREX, XRpad2 4336 HWC-M- K161966 VAREX, XRpad2 4343 HWC-M- K181526 i-Ray, Mano4336W- K201004 i-Ray, Mano4343W- K201043 Vieworks, VIVIX-S1417N (NAW, NBW)-K163703 Vieworks, VIVIX-S1717N (NAW, NBW)- K152894 VAREX, 4343W- K161459	Yes, there is a difference. An additional eight digital detectors plus the two from the predicate can be used with the system. All the flat panel detectors have been previously cleared by 510(k). The system has been tested and a risk analysis performed. There is “No negative impact on safety or efficacy” and no new potential or increased safety risks concerning were raised because of this difference.
Image Management Software			

Specification	Predicate device K192364	Subject Device	Impact of Differences
Horizontal Flip	Available	Available	None
Vertical Flip	Available	Available	None
Rotate CW/CCW	Available	Available	None
Text Annotation	Available	Available	None
Ruler: Distance tool	Available	Available	None
Angle measurement tool	Available	Available	None
Zoom	Available	Available	None
Magnify	Available	Available	None
Image panning	Available	Available	None
Auto fitting to window size	Available	Available	None
Image crop/cut function	Available	Available	None
Image Copy	Available	Available	None
Recover the original image	Available	Available	None
Window level CD Burning	Available	Available	None
DICOM Print	Available	Available	None
Image Stitching	Available	Available	None

VII. PERFORMANCE DATA

Nonclinical Testing:

Summary:

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

The complete system has been assessed and tested at the factory and by Standards testing facilities. GXR-Series Diagnostic X-Ray System, has passed all predetermined testing criteria.

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.

The following International Standards were used to develop and verify the system. GXR-Series Diagnostic X-Ray System, device has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

Std #	Safety/EMC Standards Description	FDA Consensus Standard #
IEC 60601-1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-3	Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	12-269
IEC 62366	This part of IEC 62366-1:2015 specifies a process for a manufacturer to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety	5-129

510(k) Summary of Safety

Std #	Safety/EMC Standards Description	FDA Consensus Standard #
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.	12-204
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	12-296
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	ANSI AAMI IEC 62304:2015 Medical device software - Software life cycle processes	13-79
NEMA PS 3.1	NEMA PS 3.1 - 3.20 (2016). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard.	12-300
IEC/ISO10918-1	JPEG Standard IEC/ISO10918-1 First edition 1994-02-15, Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: Technical Corrigendum 1	12-261
IEC 62494-1	IEC 62494-1 Edition 1.0 (2008-08), Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography.	12-215
ISO 14971:	ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices.	5-40
ISO 15223-1	ISO 15223-1 Third Edition 2016-11-01, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.	5-117

Conclusion:

The 510(k) Pre-Market Notification for the GXR-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 will be manufactured in accordance with the voluntary standards listed in the voluntary standard survey. The new device and predicate devices 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 device.