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

September 26, 2019

Re: K192364
Trade/Device Name: GXR-Series Diagnostic X-Ray System (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: August 27, 2019
Received: August 30, 2019

Dear Mr. Aletto:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192364

Device Name
GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S)

Indications for Use *(Describe)*

The GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S), 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K192364

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

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
TEL: +82-2-869-8566, FAX: +82-2-869-8567

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

Date Prepared: September 25, 2019

Regulatory Consultant:

Carl Alletto, OTech Inc.
215 E University Dr., Suite B
Denton, TX 76209-2011, USA
Email: carl@otechimg.com
TEL: (940) 440-9791

II. DEVICE

Product Name:	GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S)
Common Name:	Stationary X-Ray System
Classification:	Stationary x-ray system, 21 CFR 892.1680
Product Code:	KPR, MQB
Regulatory Class:	II

III. PREDICATE DEVICES

Primary Predicate Device

DIAMOND K102408, by DRGEM, product code KPR.

Reference Predicate Device

RADMAX Digital Imaging Software, K182537, by DRGEM, product code: LLZ

IV. DEVICE DESCRIPTION

The GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S) is comprised of 2 main configurations: GXR-SD and GXR-S, with SGXR-S, FDR Smart FGXR-S being different brand names for GXR-S. Both configurations are designed to diagnose the human body by providing radiographic x-ray image with anatomical structure.

GXR-S, SGXR-S, FDR Smart FGXR-S (analog) and GXR-SD (digital) have the same x-ray hardware components. However, the GXR-SD model contains image management (PACS) software and a flat panel digital detector. Interoperability is defined in the DICOM Conformance Statement which is part of the device labeling and is based upon NEMA PS 3.1 - 3.20 (2016). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard.

The GXR-S does not have image management software and does not have a digital detector.

The GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S, models consist of a high voltage (HV) generator, a tube support unit, an X-ray beam limiting device, 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 simple and 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 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.

RADMAX Digital Imaging Software (K182537) by DRGEM, is used in the GXR-SD model to serve as an interface to the hardware and images. Anatomical view-based digital image processing automatically optimizes and enhances the quality of the captured images.

Note 1: RADMAX (K182537) Digital Imaging Software (the Reference Predicate) is a digital X-ray image processing software designed for acquiring images and processing 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, filter selection, etc. for the GXR-S series.”

V. INDICATIONS FOR USE

The GXR-Series Diagnostic X-Ray System, (Models GXR-SD, GXR-S, SGXR-S, FDR Smart FGXR-S), 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

The subject device and the primary predicate device are stationary x-ray devices. There will be 2 main configurations: GXR-SD that includes a flat panel detector, and the models GXR-S, SGXR-S, FDR Smart FGXR-S do not have a detector. The GXR-Series Diagnostic X-Ray System, GXR-SD Models will use the integrated reference predicate (RADMAX K182537) device PACS image management processing software. The GXR-S, SGXR-S, FDR Smart FGXR-S models will not have image management processing software and images must be processed with other PACS workstation software.

Any differences between the subject device and the predicates and the new device has no impact on safety or efficacy 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.

Item	Subject Device		Predicate Device	Reference Predicate	Impact of Differences
Device Name	GXR-Series Diagnostic Imaging System		DIGITAL DIAGNOSTIC X-RAY SYSTEM (K102408)	RADMAX Digital Imaging System Software (K182537)	Not applicable
Manufacturer	DRGEM Corporation	DRGEM Corporation	DRGEM Corporation	DRGEM Corporation	Not applicable

DRGEM
Your Best Healthcare

510(k) Summary

Model Number	GXR-S, SGXR-S, FDR Smart FGXR-S	GXR-SD	DIAMOND 5A/6A/8A	RADMAX	Not applicable
High Frequency X-ray Generator					
Output Power	32KW, 40KW, 52KW, 68KW, 82KW	32KW, 40KW, 52KW, 68KW, 82KW	52KW, 68KW, 82KW	Not applicable, RADMAX is image management software and does not have Output Power.	Yes, there is a difference in output values but no difference in generators. See Difference Explanation below.
Generator models (manufactured by DRGEM)	GXR-32, GXR-40, GXR-52, GXR-68, GXR-82	GXR-32, GXR-40, GXR-52, GXR-68, GXR-82	GXR-52, GXR-68, GXR-82	Not applicable	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 efficacy” and there are no new potential or increased safety risks concerning this difference.
Line voltage	220~230VAC, 380/400/480VAC,	220~230VAC 380/400/480VAC	400/480VAC	Not applicable	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					
Detector	Detector not supplied with system	VAREX Model 4343R v3 Model 4336W v4	VAREX Model 4343R v3 Model 4336W v4	Not applicable	Yes, there is a difference. The model GXR-S predicate device does not have the detector as part of the system but is supplied by the User. The system has been tested and there is “No negative impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference.

Image Management Software					
Horizontal Flip	Not available	Available	Available	Available	Yes, there is a difference. The GXR-S models, does not have image processing software since there is no flat panel delivered as part of the system. The user must process images using other PACS workstations. The system has been tested and there is “No negative impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference.
Vertical Flip	Not available	Available	Available	Available	Same as above
Rotate CW/CCW	Not available	Available	Available	Available	Same as above
Text Annotation	Not available	Available	Available	Available	Same as above
Ruler: Distance tool	Not available	Available	Available	Available	Same as above
Angle measurement tool	Not available	Available	Available	Available	Same as above
Zoom	Not available	Available	Available	Available	Same as above
Magnify	Not available	Available	Available	Available	Same as above
Image panning	Not available	Available	Available	Available	Same as above
Auto fitting to window size	Not available	Available	Available	Available	Same as above
Image crop/cut function	Not available	Available	Available	Available	Same as above
Image Copy	Not available	Available	Available	Available	Same as above
Recover the original image	Not available	Available	Available	Available	Same as above
Window level CD Burning	Not available	Available	Available	Available	Same as above
DICOM Print	Not available	Available	Available	Available	Same as above
Image Stitching	Not available	Available	Available	Available	Same as above

VII. PERFORMANCE DATA

Nonclinical Testing:

The GXR-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.

Summary:

510(k) 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 following International Standards were used to develop and verify electrical safety, and EMC. 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).

The subject device conform to all applicable aspects of 21CFR 1020.30-31.

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 62366	IEC 62366:2007 + A1:2014 – Usability engineering process checklist	5-114
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
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	12-296
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 62304:2006	ANSI AAMI IEC 62304:2006 Medical device software - Software life cycle processes	13-32
IEC 60601-1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-4
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 14971:2007	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
FDA Guidance	Pediatric Information for X-ray Imaging Device Premarket Notifications dated November 28, 2017	Not applicable
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	Not applicable

Std #	Safety/EMC Standards Description	FDA Rec. Standard #
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	Not applicable
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	Not applicable

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for IntelePACS, contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The new device and the primary 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.