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

September 10, 2020

Re: K202156
Trade/Device Name: DIAMOND-5A/6A/8A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: August 15, 2020
Received: August 19, 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)*
K202156

Device Name
DIAMOND-5A/6A/8A

Indications for Use *(Describe)*

DIAMOND-5A/6A/8A, is a stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammography, bone density, fluoroscopy and angiography 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.***

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# 510(k) Summary of Safety

Submission number: K202156

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

Date Prepared: August 11, 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: DIAMOND-5A/6A/8A
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

The DIAMOND-5A/6A/8A subject device is substantially equivalent to: DIAMOND-5A/6A/8A (K192453), by DRGEM, product code KPR. Regulation 21 CFR 892.1680

## IV. DEVICE DESCRIPTION

DIAMOND-5A/6A/8A, system is a digital radiographic system. There are 3 power output configurations which are reflected in the model designation “5A/6A/8A”. The models have 3 different output power ratings:

| System Model | DIAMOND-5A | DIAMOND-6A | DIAMOND-8A |
|---|---|---|---|
| X-Ray Generator | GXR-52 | GXR-68 | GXR-82 |
| Output Rating | 52kW | 68kW | 82kW |

DIAMOND 5A/6A/8A, incorporates digital flat panel detector technology, along with an automatic motorized U-arm radiographic stand and mobile patient table that can fit into smaller rooms without the need of ceiling support structures for X-Ray tube suspensions. The subject device comes in 2 hardware configurations; a Radiographic Stand configuration for a wired detector and a Radiographic Stand for removable detectors. The main components of the subject device are the same as the predicate. Components of the x-ray source are the tube assembly, motorized x-ray collimator, HV cable assembly and high frequency x-ray generator. A touch screen LCD based x-ray control console provides a user interface and technique selection. The automatic collimator supports high accuracy for selected x-ray field size over SID.

Selection of an anatomical study on the imaging software automatically sets up the x-ray generator’s pre-programmed exposure technique setting, motorized radiographic stand positioning, x-ray collimation and post image processing for selected study. Also, removable high-resolution grids which have 100 and 180cm (40 and 72 inch) focal distance. The integrated touch screen console located on the tube side, operator can easily control the radiographic techniques and stand positioning. Furthermore, the operator can verify the digital x-ray image on this screen. The GUI, automatically rotates corresponds to rotation angle of U-arm.

- Selection of an anatomical study on the imaging software, (RADMAX), automatically sets up the x-ray generator's pre-programmed exposure technique setting, motorized radiographic stand positioning, x-ray collimation and post image processing for selected study. Also, removable high-resolution grids which have 100 and 180cm (40 and 72 inch) focal distance supplies excellent image quality per each SID. The integrated touch screen console located in the tube side, operator can easily control the radiographic techniques and stand positioning. Furthermore, the operator can verify the digital x-ray image on this screen. The GUI, automatically rotates corresponds to rotation angle of U-arm.
- The Radiographic stand has four motorized joints, and automatic positioning can be accomplished by preprogrammed data which can be easily reprogrammed by operator. Total of seven safety sensors are located over U-arm, detector and tube side to protect against collision with patient or obstacles to control the speed or stop the positioning. Also, a mobile patient table with heavy patient load is provided for radiographic study which needs table. A remote-control is provided for remote motorized control of the stand, and the movement will stop as soon as the key is no longer pressed.
- The subject device contains the same image handling software as the predicate device called RADMAX. RADMAX Digital Imaging Software, was cleared under K182537 and used in the predicate. RADMAX can perform image management and system control such as the collimation size, filter selection, etc. for the GXR series x-ray generators.

DIAMOND 5A/6A/8A, incorporates digital flat panel detector technology, along with an automatic motorized U-arm radiographic stand and mobile patient table that can fit into smaller rooms without the need of ceiling support structures for X-Ray tube suspensions.

The digital flat panel digital detectors that are used in the subject device are:

- Fujifilm, DR-ID 1272SE/ DR-ID 1274SE cleared under K142003
- Varex, PaxScan4343W cleared under K161459, and
- i-Ray, Mano4343W cleared under K201043.
- In addition to VAREX Model 4343Rv3 (Ethernet interface) and 4336Wv4 (wireless), used in the predicate.

## V. INDICATIONS FOR USE

DIAMOND-5A/6A/8A, is a stationary digital diagnostic x-ray system that is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammography, bone density, fluoroscopy and angiography applications.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Summary of differences:

The subject device can use three previously cleared digital flat panel detectors in addition to the detectors used in the predicate device. The added detectors are:

- Fujifilm, DR-ID 1272SE/ DR-ID 1274SE cleared under K142003
- Varex, PaxScan4343W cleared under K161459
- i-Ray, Mano4343W cleared under K201043

The following information compares the subject device to the predicate and subject device.

Any differences between the subject device and the predicated device has 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 - K192453 | Subject Device | Impact of Differences |
|---|---|---|---|
| Device Name | DIAMOND 5A/6A/8A | DIAMOND 5A/6A/8A | No difference |
| Manufacturer | DRGEM Corporation | DRGEM Corporation | No difference |
| Model Number | DIAMOND 5A/6A/8A | DIAMOND 5A/6A/8A | No difference |
| **High Frequency X-ray Generator** | | | |
| Output Power | 52KW, 68KW, 82KW | 52KW, 68KW, 82KW | No difference |
| Generator models (manufactured by DRGEM) | GXR-52, GXR-68, GXR-82 | GXR-52, GXR-C52, GXR-68, GXR-82 | GXR-C52 X-Ray Generator is added and uses single phase 220/230V whereas the other generator models use 3 phase 380/400/480V |
| **Image Acquisition** | | | |
| Detectors | VAREX, Model 4343Rv3 | • VAREX, Model 4343Rv3<br>• Fujifilm, Models DR-ID 1272SE/DR-ID 1274SE<br>• Varex, Model PaxScan4343W<br>• i-Ray, Model Mano4343W | Differences: 3 additional flat panel detectors:<br>Fujifilm; K142003<br>Varex; K161459<br>iRAY; K201043<br>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 these differences. |
| Image Management Software & System control | RADMAX Digital Imaging Software - K182537 | RADMAX Digital Imaging Software - K182537 | No significant differences. RADMAX in the subject device is the latest Image Management software, version 1.01. 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. |

**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. DIAMOND-5A/6A/8A, 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. DIAMOND-5A/6A/8A, device has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

The main components of DIAMOND-5A/6A/8A comply with the regulatory requirements and design standards in this section as follows:

| **Std #** | **Safety/EMC Standards Description** | **FDA Rec. Standard #** |
|---|---|---|
| IEC 60601-1-3 | Medical electrical equipment<br>Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment | 12-269 |
| IEC 62366 (IEC 60601-1-6) | IEC 62366:2007 + A1:2014 – Usability engineering process checklist | 5-114 |
| IEC 60601-2-28 | IEC 60601-2-28<br>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<br>Medical electrical equipment<br>Part 2: Particular requirements for the basic safety and essential<br>performance of X-ray equipment for radiography and radioscopy | 12-296 |
| IEC 62304:2006 | ANSI AAMI IEC 62304:2006<br>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 |
| 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 |

| Std # | Safety/EMC Standards Description | FDA Rec. Standard # |
|---|---|---|
| IEC 62366-1:2015 | This part of IEC 6 2366 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 |

Conclusion:

The 510(k) Pre-Market Notification for the DIAMOND-5A/6A/8A, 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.