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

October 1, 2019

Re: K192453
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: September 2, 2019
Received: September 9, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192453

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 mammographic 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.

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510(k) Summary - K192453

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
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Gwangmyeong-si, Gyeonggi-do, 14322 Korea
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Contact Person: Mr. Ki-Nam YANG, Director | QM representative

Date Prepared: September 22, 2019

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 DEVICES

Primary Predicate Device

DIGITAL DIAGNOSTIC X-RAY SYSTEM (K102408) (DIAMOND), by DRGEM, product code KPR. Regulation 892.1680

Reference Predicate Device

RADMAX Digital Imaging Software, K182537, by DRGEM, product code: LLZ. Regulation 892.2050

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 digital flat panel digital detectors that are used in DIAMOND-5A/6A/8A, are the VAREX Model 4343Rv3 (Ethernet interface) and 4336Wv4 (wireless). The Model 4343Rv3 (Ethernet interface) was cleared with the primary predicate device and both the Model 4343Rv3 (Ethernet interface) and 4336Wv4 (wireless) were cleared with RADMAX the reference predicate device.

The main 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 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 predicate device contains image handling software that was designed at the same time the product was originally developed. The subject device will replace the original image handling module with the RADMAX Digital Image Software cleared under K182537. This will improve the software changeability when a change is needed and also will improve cyber security since there was no documented cyber security plan at the time of the original product development. RADMAX can also perform system control such as the collimation size, filter selection, etc. for the GXR series x-ray generators.

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 mammographic applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject device and the predicate device are stationary digital x-ray systems devices. The predicate device, K102408, DIGITAL DIAGNOSTIC X-RAY SYSTEM (DIAMOND) from DRGEM and the reference predicate device K182537, RADMAX Digital Imaging Software are being merged. The reference predicate device is replacing the digital imaging handling software module that was originally developed for the predicate. The intended use of the modified device, as described in the labeling, has not changed as a result of the modification.

Any difference between the subject device and the predicate device does not affect safety or efficacy. No other changes were made to the predicate, besides the stated differences.

Specification	Subject Device	Predicate Device (K102408)	Reference Predicate RADMAX (K182537)	Impact of Differences
Device Name	DIAMOND 5A/6A/8A	DIGITAL DIAGNOSTIC X-RAY SYSTEM	RADMAX Digital Imaging System Software	Not applicable
Manufacturer	DRGEM Corporation	DRGEM Corporation	DRGEM Corporation	Not applicable
Model Number	DIAMOND 5A/6A/8A	DIAMOND 5A/6A/8A	RADMAX	Not applicable

510(k) Summary

Specification	Subject Device	Predicate Device (K102408)	Reference Predicate RADMAX (K182537)	Impact of Differences
High Frequency X-ray Generator				
Output Power	52KW, 68KW, 82KW	52KW, 68KW, 82KW	Not applicable, RADMAX is image management software and does not have Output Power.	No differences
Generator models (manufactured by DRGEM)	GXR-52, GXR-68, GXR-82	GXR-52, GXR-68, GXR-82	Not applicable	No differences
Line voltage	400/480VAC	400/480VAC	Not applicable	No differences
Image Acquisition				
Detector	VAREX Model 4343Rv3 (Ethernet)/ 4336W v4 (wireless)	VAREX Model 4343Rv3 (Ethernet)	VAREX Model 4343Rv3 (Ethernet)/ 4336W v4 (wireless)	The predicate device uses an Ethernet interface and the subject device interfaces to either Ethernet or wireless detectors. The detectors were cleared with the primary predicate and reference predicate. The subject device 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	Available	Available	Available	These features between the Primary Predicate, Reference Predicate and Subject device are similar. There may be some rearrangement of headers and or button locations since RADMAX is the latest Image Management software. The subject device 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	Available	Available	Available	Same as above
Rotate CW/CCW	Available	Available	Available	Same as above
Text Annotation	Available	Available	Available	Same as above
Ruler: Distance tool	Available	Available	Available	Same as above
Angle measurement tool	Available	Available	Available	Same as above
Zoom	Available	Available	Available	Same as above
Magnify	Available	Available	Available	Same as above
Image panning	Available	Available	Available	Same as above
Auto fitting to window size	Available	Available	Available	Same as above
Image crop/cut function	Available	Available	Available	Same as above

Specification	Subject Device	Predicate Device (K102408)	Reference Predicate RADMAX (K182537)	Impact of Differences
Image Copy	Available	Available	Available	Same as above
Recover the original image	Available	Available	Available	Same as above
Window level CD Burning	Available	Available	Available	Same as above
DICOM Print	Available	Available	Available	Same as above
Image Stitching	Available	Available	Available	Same as above

VII. PERFORMANCE DATA

Nonclinical Testing:
The DIAMOND-5A/6A/8A 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:

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 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):

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 60601-1-6)	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 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

Std #	Safety/EMC Standards Description	FDA Rec. Standard #
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

VIII. CONCLUSIONS

The 510(k) Pre-Market Notification for 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 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.