March 8, 2019

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

Re: K182537
Trade/Device Name: RADMAX Digital Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 11, 2019
Received: January 29, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182537

Device Name
RADMAX Digital Imaging Software

Indications for Use *(Describe)*

The RADMAX Digital Imaging Software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, and image processing.
The RADMAX Digital Imaging Software, is not intended for the acquisition of mammographic image data.
The X-ray generator is not part of the RADMAX Digital Imaging Software, device.
If the X-ray generator does not allow interfacing with external software the RADMAX Digital Imaging Software device cannot be interfaced with X-ray Generator.
However, when using third-party generator, use the AED function to acquire the image by sensing the X-ray photon.
When using the DRGEM Corporation, generator (models GXR, GXR-C, GXR-U), the RADMAX Digital Imaging Software can only select or change values of X-ray exposure parameters (kVP, mA, Time, or kVP, mAs or kVP, mA or density).

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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K182537

510(k) Summary of Safety

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.87(h):

Date Prepared:

January 9, 2019

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Ki-Nam YANG
Director | QM representative
DRGEM Corporation
7F E-B/D Gwangmyeong Techno-Park 60, Haan-ro,
Gwangmyeong-si, Gyeonggi-do, 14322 Korea
Email: radcheck@drgem.co.kr

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Product Name: RADMAX Digital Imaging Software

Common Name: Picture, archive and communications system

Classification Name: System, Image Processing, Radiological

Product Code: LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

The RADMAX Digital Imaging Software is substantially equivalent to K123650:

Device Classification Name	System, Image Processing, Radiological
510(K) Number	K123650
Device Name	ARIX RAD ACQUISITION CONSOLE
Applicant	COMPANIA MEXICANA DE RADIOLOGIA CGR, S.A. DE C.V.
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	02/20/2013
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
Summary	Summary
Type	Traditional

Device Description: 21 CFR 807 92(a)(4)

The RADMAX Digital Imaging Software from DRGEM Corporation, is a digital X-ray image processing system 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 software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, and image processing.

The X-ray generator or digital detector is not part of the RADMAX Digital Imaging Software, device. The RADMAX Digital Imaging Software does not control exposure or electrical charge and X-ray calibration. If the X-ray generator does not allow interfacing with external software like the RADMAX Digital Imaging Software device, then the software cannot be interfaced with X-ray

Generator. The RADMAX Digital Imaging Software can only select or change values of X-ray exposure parameters (kVp, mA second or kVp; mAs) according to the defined value determined by each X-ray company.

The RADMAX Digital Imaging Software, is not intended for the acquisition of mammographic image data.

The RADMAX Digital Imaging Software device is not intended for the acquisition of mammographic image data and is meant to be used by qualified medical personnel only. The Users must be qualified to create and diagnose radiological image data.

The main functions of the RADMAX Imaging Software are as follows:

- Acquisition and storage of digital X-ray images from a digital X-ray Detector.
- Input Study information (patient information, exam information).
- Management of stored (archived) images.
- Image processing for enhancement of archived images.
- Review of stored images.
- Editing of images.
- DICOM conformance (e.g. DICOM Storage, DICOM Work list, DICOM Print, etc.)
- For a DR system (X-ray machine and generator and Digital X-ray detector, etc.) or a need to interface with installed X-ray system, the:
  - Ability to configure X-ray exposure condition (kVp, mA, Sec etc) for various body parts and positions.
  - Communication between the Generator Console and the RADMAX device.

The X-ray generator control function depends on the X-ray Generator company. The X-ray generator is not part of the RADMAX Digital Imaging Software device since the RADMAX device can only interface and control the Generator by the algorithm provided by the X-ray Company. The RADMAX device can only select or change values of X-ray exposure parameters (kVp, mA second or kVp; mAs) according to the defined value determined by each X-ray company.

The RADMAX Digital Imaging Software, device does not control exposure or electrical charge and or calibration of the X-ray equipment. If the X-ray generator does not allow interfacing with an external software like the RADMAX Imaging Software, then RADMAX, cannot be interfaced with the X-ray Generator.

Indications for Use: 21 CFR 807 92(a)(5)

The RADMAX Digital Imaging Software, used together with a digital X-ray detector is a digital X-ray image processing system designed for acquiring images and processing acquired images. The main features of the software are controlling and interfacing the detector, acquiring images after X-ray, storing acquired images, managing data, and image processing. The RADMAX Digital Imaging Software, is not intended for the acquisition of mammographic image data.

The X-ray generator is not part of the RADMAX Digital Imaging Software, device.

If the X-ray generator does not allow interfacing with external software the RADMAX Digital Imaging Software device cannot be interfaced with X-ray Generator.

However, when using third-party generator, use the AED function to acquire the image by sensing the X-ray photon. When using the DRGEM Corporation, generator (models GXR, GXR-C, GXR-U), the RADMAX Digital Imaging Software can only select or change values of X-ray exposure parameters (kVP, mA, Time, or kVP, mAs or kVP, mA or density).

510(k) Summary of Safety

Technological Characteristics: 21 CFR 807 92(a)(6)

RADMAX Digital Imaging Software, is a software device that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the software but by Radiologists, Clinicians and or referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

The subject device does not raise any new potential safety risks and is equivalent in performance to the existing legally marketed devices. Both systems have been developed to replace traditional film handling in radiology. The 2 devices are substantially equivalent in the areas of design, architecture, general function, application, and intended use.

The following table compares the predicate device and the new device. Any differences between the predicate 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	Functionality	Subject Device: RADMAX Digital Imaging Software	Predicate K123650 ARiX RAD Acquisition Console	If different, Impact on Safety and or Efficacy
1	Computer & Operating System	Microsoft Windows 10 (minimum)	Microsoft Windows XP/Windows 7 (minimum)	Yes, there is a difference. Differences are in the processor speeds, Windows operating system, amount of RAM memory, monitors, and hard drive space requirements. These differences are due to the state of computer technology that was available at the time the predicate device was developed. There is "No impact on safety or efficacy" and there are no new potential or increased safety risks.
2	Intended use	Acquiring, viewing, editing and storing radiographs and related patient images	Same	No difference
3	Intended user	radiologist	radiologist	No difference
4	Network	10/100/100 Ethernet	Same	No difference
5	Monitor	Two color display adaptors 1920x1080	19-inch monitor using 1280x1024	Yes, there is a difference. See item 1 above.
6	User interaction/input	Mouse, keyboard, touch monitor	Same	No difference
7	Multi-user	Available, but at a time, only one user can use it	Same	No difference
8	Import / export images	Yes	Yes	No difference
9	Acquisition devices	Digital X-Ray detectors	Digital X-Ray detectors	No difference
10	Imaging interfaces	Detector dependent	Detector dependent	Yes, there is a difference. Subject device uses Flat panel detectors cleared by FDA: K171138, & K172951
11	Image organization	Yes. Patient ID, Name, study instance UID	Same	No difference
12	Image search available	Yes	Yes	No difference
13	Image storage	Yes	Yes	No difference
14	Database software	MySQL	MySQL	No difference
15	Image viewing	Yes	Yes	No difference
16	Image measurement	Yes	Yes	No difference
17	Image annotation	Yes	Yes	No difference
18	Image operations	Yes	Yes	No difference
19	Security	Yes (Priority by user)	Same	No difference
20	DICOM 3.0 compatibility	Yes	Yes	No difference
21	Generator Control	Yes	Yes	No difference
22	Generator Control Protocol	Generator dependent	Generator dependent	No difference

510(k) Summary of Safety

Item	Functionality	Subject Device: RADMAX Digital Imaging Software	Predicate K123650 ARiX RAD Acquisition Console	If different, Impact on Safety and or Efficacy
23	RAW Image data processing	Yes	Yes	No difference
24	Post image data processing	Yes	Yes	No difference
25	RIS code manager	Yes	Yes	No difference
26	Worklist	Yes	Yes	No difference
27	Patient size/Laterality	Yes	Yes	No difference
28	Display radiographic technique, kV, mA, ms, mAs	Yes	Yes	No difference
29	Thumbnail viewing	Yes	Yes	No difference
30	Login	Yes	Yes	No difference
31	New patient manual register	Yes	Yes	No difference
32	X-Ray generator window	Yes	Yes	No differences
33	Bucky selection	Yes	Yes	No difference
34	Body part	Yes	Yes	No difference
35	Generator status display	Yes	Yes	No difference
36	Image reset	Yes	Yes	No difference
37	panning	Yes	Yes	No difference
38	Magnify glass	Yes	Yes	No difference
39	Fit image	Yes	Yes	No difference
40	Image Stitching	Yes	Yes	No difference
41	Series/Image list	Yes	Yes	No difference

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all predetermined in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by the RADMAX Digital Imaging Software 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.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the RADMAX Digital Imaging Software, device 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 as well as the predicate device.

Therefore, RADMAX Digital Imaging Software, is substantially equivalent to the predicate device.