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

May 19, 2020

Re: K201124
Trade/Device Name: TOPAZ Mobile DR System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: April 24, 2020
Received: April 27, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201124

Device Name
TOPAZ Mobile DR System

Indications for Use *(Describe)*

The TOPAZ Mobile DR System, is a mobile 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, 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
K201124

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

Date Prepared: May 14, 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

Name of Device:	TOPAZ Mobile DR System
Common or Usual Name:	Mobile x-ray system
Regulation Name:	Mobile x-ray system
Regulation:	21 CFR 892.1720
Product Code:	IZL
Regulatory Class:	II

III. PREDICATE DEVICE

The TOPAZ Mobile DR System device is substantially equivalent to:

Device Classification Name	Mobile X-Ray System
510(K) Number	K183292
Device Name	Topaz Mobile DR System
Applicant	DRGEM Corporation 7F E-B/D Gwangmyeong Techno-Park 60, Haan-Ro Gwangmyeong-Si, KR 14322
Regulation Number	892.1720
Classification Product Code	IZL
Decision Date	05/15/2019
Regulation Medical Specialty	Radiology

IV. DEVICE DESCRIPTION

The TOPAZ Mobile DR System, (TOPAZ), is a mobile x-ray system and is a modification of the predicate device. There are 2 models for TOPAZ: TOPAZ-32D (32KW) and TOPAZ-40D (40KW). TOPAZ, may be moved quietly and smoothly with a motor drive mechanism.

The core part of x-ray source is a 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-friendly interface and technique selection. The Collimator supports high accuracy for selected x-ray field size over any SID. Selection of an anatomical study on the imaging software automatically sets up the x-ray generator's pre-programmed exposure technique.

The X-ray passing through a patient's body is sent to the detector and then converted into electrical signals. These signals go through the process of amplification and digital data conversion in the signal process on the workstation and saved in a DICOM file for review on the device or on a Picture Archiving & Communication System (PACS) workstation. The digital detector type used in the predicate TOPAZ is "VARIAN PacScan4336W" or "VARIAN

PacScan4336W_V4 which was cleared as part of the Nexus DR™ Digital X-ray Imaging System (with PaxScan 4336Wv4), K161459. The modified device can use five additional digital detectors which also have been previously cleared by 510(k): XRpad2 3025 HWC - K161942, XRpad2 4336 HWC - K161966, XRpad2 4343 HWC - K181526, Mano4343W - K183713, and Mano4336W - K182551.

The TOPAZ Workstation Image Management features and functions are as follows in both the predicate and modified device:

- ROI: Default 13 ROI support
- MARK: Unlimited support (User preset support)
- Horizontal Flip
- Vertical Flip
- Rotate Clockwise (CW)
- Rotate Counter Clockwise (CCW)
- Inverse (Black or White)
- Text Annotation
- Caliper / Ruler: Distance tool
- Angle: Angle measurement tool
- Zoom: Image zoom in/out
- Magnify: Image magnify glass window
- Pan: Image panning

V. INDICATIONS FOR USE

The TOPAZ Mobile DR System, is a mobile 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, bone density, fluoroscopy and angiography applications.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

TOPAZ Mobile DR System is a mobile x-ray system.

Summary of differences:

The difference between the predicate device and the modified device is the addition of five previously cleared x-ray detectors to the TOPAZ system. The added detectors are:

- XRpad2 3025 HWC - 510(k) number K161942
- XRpad2 4336 HWC – 510(k) number K161966
- XRpad2 4343 HWC – 510(k) number K181526
- Mano4343W – 510(k) number K183713
- Mano4336W – 510(k) number K182551

VII. PERFORMANCE DATA

Nonclinical Testing:

The complete system has been assessed and tested at the factory and by Standards testing facilities. The TOPAZ Mobile DR System has passed all predetermined testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and actions performed by TOPAZ, 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.

The following Standards were used to test the system and TOPAZ Mobile DR System, has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports):

- IEC 60601-2-54 Ed. 1.0:2009, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (including Technical Corrigendum 1: 2010 and Technical Corrigendum 2:2011) FDA Recognized Standard #12-296.
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD). FDA Recognized Standard #19-4.
- IEC 60601-1-6 Edition 3.1 2013-10, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. FDA Recognized Standard #5-89.
- IEC 60601-1-3 Edition 2.1 2013-04, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment. FDA Recognized Standard #12-269.
- IEC 60601-2-28 Edition 2.0 2010-03. Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis. Recognized Standard #12-204.
- ANSI AAMI IEC 62304:2006. Medical device software - Software life cycle processes. FDA Recognized Standard #13-32.
- 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. FDA Recognized Standard #19-8.
- NEMA PS 3.1 - 3.20 (2016). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard. FDA Recognized Standard #12-300.
- 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 (2005)]. FDA Recognized Standard #12-261.
- 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. FDA Recognized Standard #12-215.
- ANSI AAMI ISO 14971:2007/(R)2010 (Corrected 4 October 2007), Medical devices - Applications of risk management to medical devices. FDA Recognized Standard #05-40.
- 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. FDA Recognized Standard #05-117.

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

The 510(k) Pre-Market Notification for the TOPAZ Mobile DR 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 as well as the predicate device.

Therefore, the TOPAZ Mobile DR System, is substantially equivalent to the predicate device.