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

May 15, 2019

Re: K183292
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 23, 2019
Received: April 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,

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)*
K183292

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.

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510(k) Summary

K183292

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

Date Prepared:

April 23, 2019

Submitter's Information:

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

Product Name:	TOPAZ Mobile DR System
Common Name:	Mobile X-Ray System
Classification Name:	Mobile X-Ray System
Regulation Number:	892.1720
Device Classification:	Class II
Product Code:	IZL

Predicate Device:

The TOPAZ Mobile DR System is substantially equivalent to K181626:

Device Classification Name	Mobile x-ray system
510(K) Number	K181626
Device Name	Digital Diagnostic Mobile X-Ray System
Applicant	Samsung Electronics Co., Ltd.
Regulation Number	892.1720
Classification Product Code	IZL
Decision Date	07/20/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Summary	Summary

Reference Predicate Device:

Device Classification Name	Stationary x-ray system
510(K) Number	K161459
Device Name	Nexus DRTM Digital X-Ray Imaging System (With PaxScan 4336Wv4)

510(k) Summary

Applicant	VARIAN MEDICAL SYSTEMS, X-RAY PRODUCTS-INFIMED
Regulation Number	892.1680
Classification Product Code	MQB
Date Received	05/26/2016
Decision Date	09/06/2016
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Radiology
510k Review Panel	Radiology
Summary	Summary

Device Description:

The TOPAZ Mobile DR System, (TOPAZ), is a mobile x-ray system. 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.
Direct radiography via a flat panel detector improves workflow, exam speed and user comfort with efficiency. Digital flat panel detector with CsI screen provides good spatial resolution, MTF, DQE and stability based on a fine pixel pitch. The digital detector type used in 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.

Note: K161459 is being used as a "Reference Predicate Device". The IFU: "The Varian Nexus DR™ Digital X-ray Imaging System is a high-resolution digital imaging system intended to replace conventional film techniques.

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 Workstation Image Management features and functions are:

- 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

510(k) Summary

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.

Technological Characteristics:

TOPAZ Mobile DR System is a mobile x-ray system. The TOPAZ specifications are in TABLE 1. The x-ray detector included with this device has been previously-cleared with the reference predicate.

TABLE 2, 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.

Note:
The x-ray detector included with the subject device has been previously-cleared with the reference predicate device K161459.

TABLE 1

Item		**Specification**	
		TOPAZ-32D	**TOPAZ-40D**
X-ray Generator	Nominal Output	32KW	40KW
	mA Range	Max. 400mA	Max. 500mA
	KV Range	40 ~ 125 KV (option: 150KV)	40 ~ 125 KV (option: 150KV)
	mAs Range	0,1 ~ 500mAs	0,1 ~ 500mAs
	Operation Duty Cycle	100kV, 320mA, 100ms / Rest time: 1min	100kV, 400mA, 100ms / Rest time: 1min
	Type	High Frequency	
System Design & Transport	Drive Type	Motor Driven (Rear-wheel drive)	
	Speed of Movement	Max. 5Km/h	
	Movement Brake/ Safety	Deadman type Handle, Front Safety Bumper, Spring Caster	
	Maximum Step Height	50mm	
	Maximum ramp gradient	10 degrees	
	Main power supply	100 ~ 240VAC, 9 – 4 A	
	Cable Length (Mains, retractable)	3m	
	Driving distance after fully charged	30km	
	Inch mover	Max. 50mm/s	
X-Ray Tube Support	Colum rotation range	± 325 degrees	
	Tube axis rotation range	-30 ~ +90 degrees	
	Tube support axis rotation range	± 180 degrees	
	Collimator rotation range	± 120 degrees	
	Max./Min. X-ray focal spot height	1,390mm (Option: 1200mm)	
	Max. horizontal extension	560mm	

510(k) Summary

Item		Specification	
		TOPAZ-32D	TOPAZ-40D
Option & Accessories	Remote Controller	Ready-Exposure, Lamp On/Off	
	DAP (Dose Area Product) Recording	Thermal Printer	

TABLE 2

Specification	Subject Device	Predicate Device	Reference Predicate	Discussion
Device Name	TOPAZ Mobile DR X-ray System	GM85	Nexus DR Digital X-ray Imaging System (with PaxScan 4336Wv4)	
Manufacturer	DRGEM Corporation	Samsung Electronics Co, Ltd.	Varian Medical Systems	-
510(k) Number	K183292	K181626	K161459	-
Appearance		  [C-Type*] [F-Type**] *Collapsible column type (C-Type) **Fixed column type (F-Type)		The reference predicate does not have an x-ray source. Major system components include an image receptor, computer, monitor and imaging software
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	The GM85 Digital Mobile X-ray imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not	The Varian Nexus DR™ Digital X-ray Imaging System is a high-resolution digital imaging system intended to replace conventional film techniques, or existing digital systems, in	The subject device and predicate are similar since both are mobile X-ray systems.

510(k) Summary

Specification	Subject Device		Predicate Device	Reference Predicate	Discussion
	mammography, bone density, fluoroscopy and angiography applications.		intended for mammographic applications.	multipurpose or dedicated applications specified below. The Nexus DR™ Digital X-ray Imaging System enables an operator to acquire, display, process, export images to portable media, send images over a network for long term storage and distribute hardcopy images with a laser printer.	
X-ray Generator					
Nominal Output	32KW	40KW	32kW / 40kW	Not Applicable	Same
mA Range	Max. 400mA	Max. 500mA	Max. 500mA	Not Applicable	Same
KV Range	40 ~ 125 KV (option: 150KV)	40 ~ 125 KV (option: 150KV)	40 ~ 125 KV (option: 150KV)	Not Applicable	Same
mAs Range	0,1 ~ 500mAs	0,1 ~ 500mAs	0 - 500mAs	Not Applicable	Same
Tube Assembly					
Tube type	Toshiba: E7239X, E7242X, E7299X, E7876X DRGEM: DXT-8M, DXT-11M, DXT-10M, DXT-12M		LUCEM Corporation: LUC-13L, Toshiba: XRR-3332X	Not Applicable	Difference 1
Focal spot	1.0/2.0mm, 0.3/1.0mm, 0.6/1.5mm		0.6/1.2mm	Not Applicable	Difference 2
Target angle	12° to 16 depending upon the Tube		12° to 16° depending upon the Tube	Not Applicable	Same
Colum rotation range	± 325 degrees		±315°	Not Applicable	Difference 3
Tube (Arm axis)	± 180 degrees		±180 degrees	Not Applicable	Same
Tube axis rotation range	30 ~ +90 degrees		-30°~90°	Not Applicable	Same

510(k) Summary

Specification	Subject Device	Predicate Device	Reference Predicate	Discussion
Max Tube Voltage	150kV	150kV	Not Applicable	Same depending upon the tube model
Detectors				
Name	Varian PaxScan 4336W_v4 Varian PaxScan 4336W	Samsung Model S4335-W Samsung Model S4343-W Samsung Model S3025-W Samsung Model S4335-AW Samsung Model S4343-AW	Varian PaxScan 4336W_v4 Varian PaxScan 4336W	Difference 4
Detector Type	CsI	CsI	CsI	Same
Detector Dimensions	17" x 14"	17" x 14"	17" x 14"	Same
Pixel Size	140 X 140	140 X 140 microns	140 X 140 microns	Same
Detector Element Matrix	3072 x 2560	2466X3040 or 3036X3040 depending upon the detector model	3072 x 2560	Difference 5
Spatial Resolution	3.2 lp/mm	3.57 lp/mm	3.2 lp/mm	Difference 6

Difference 1: There are many x-ray tubes available due to equipment design considerations. The TOPAZ tubes were tested (data included with submission) and information is included in the Operator and Service Manuals. Any differences between the subject device and predicate device do not change or add new potential safety risks. Therefore, it is our determination that there is "No impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.

Difference 2: The focal spot on the x-ray tube is different between the subject device and the predicate. The "focal spot" is the area of the anode surface which receives the beam of electrons from the cathode. The size and shape of the focal spot is determined by the size and shape of the electron beam when it strikes the anode. Size and shape of the electron beam is determined by: dimensions of the filament tungsten coil, construction of the focusing cup, and position of the filament in the focusing cup. Since the subject device and predicate are using different x-ray tub manufactures, the focal spot is different. The differences between the subject device and predicate device do not change or add new potential safety risks. Therefore, it is our determination that there is "No impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.

Difference 3: The Colum Rotation R on the subject device is 325 degrees and the predicate is 315 degrees. The increased subject device range can make it easier to position the device. Therefore, it is our determination that there is "No impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.

Difference 4: The subject device uses the Varian PaxScan 4336W detector cleared in K161459 (Nexus DR Digital X-ray Imaging System while the predicate uses a detector manufactured by Samsung. Any differences between the subject device and predicate device do not change or add new potential safety risks. Therefore, it is our determination that there is "No impact on safety or efficacy" and there are no new potential or increased safety risks concerning this difference.

Difference 5: The detectors in the subject device have an approximate pixel count of 7.5 and 9.3 MP while the predicate device has approximately 7.9 MP. The x-ray detector included with the subject device has been previously-cleared with the reference predicate device K161459. Any differences between the subject device and predicate device do not change or add new potential safety risks. Therefore, it is our

determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference.

Difference 6: The subject device has a slightly higher special resolution (3.57) then the predicate at 3.2. Spatial resolution refers to the number of pixels utilized in construction of the image. Images having higher spatial resolution are composed with a greater number of pixels than those of lower spatial resolution. The differences between the subject device and predicate device do not change or add new potential safety risks. Therefore, it is our determination that there is “No impact on safety or efficacy” and there are no new potential or increased safety risks concerning this difference.

Clinical Testing:

Clinical testing is not necessary for the TOPAZ Mobile DR system in order to demonstrate substantial equivalence to the predicate device.

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 #12-24.
- 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:

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