December 16, 2024

DRGEM Corporation
℅ Arim Kim
Regulatory Affairs | Engineer
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GwangMyeong-si, Gyeonggi 14322
SOUTH KOREA

Re: K242015
Trade/Device Name: TOPAZ Mobile X-ray System (Models : TOPAZ-32D, TOPAZ-40D)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: July 10, 2024
Received: December 3, 2024

Dear Arim Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

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Diagnostic X-Ray Systems Team
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OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242015

Device Name
TOPAZ Mobile X-ray System (Models: TOPAZ-32D, TOPAZ-40D)

Indications for Use *(Describe)*

The 'TOPAZ Mobile X-ray System' is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis.

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

K242015

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER [21 CFR 807.92(a) (1)]

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Date Prepared: June 15, 2024

II. PROPOSED DEVICE INFORMATION [21 CFR 807.92(a) (2)]

Product Name: TOPAZ Mobile X-ray System (Models: TOPAZ-32D, TOPAZ-40D)
Common Name: Mobile x-ray system
Classification Name: Mobile x-ray system
Product Code: IZL
Regulation Number: 892.1720
Associated Product Code: MQB
Regulatory Class: II

III. PREDICATE DEVICES INFORMATION [21 CFR 807.92(a) (3)]

Product Name: TOPAZ Mobile DR System (Models: TOPAZ-32D, TOPAZ-40D)
Common Name: Mobile x-ray system
Classification Name: Mobile x-ray system
510(k) Number: K201124
Product Code: IZL
Regulation Number: 892.1720
Regulatory Class: II

IV. DEVICE DESCRIPTION [21 CFR 807.92(a) (4)]

● **Device Features:**

· TOPAZ Mobile X-ray System

"TOPAZ" system is a system providing state-of-the-art image quality, user interface.

"TOPAZ" system may be moved quietly and smoothly with motor drive mechanism

"TOPAZ" system has a basic type column, and a collapsible type column option with a trendy design that allows driving without disturbing the front view.

The core part of x-ray source adopts high quality tube assembly, motorized x-ray collimator, HV cable assembly and High Voltage X-Ray Generator. Touch screen LCD based x-ray control console provides user-friendly interface and easy technique selection. Collimator supports high accuracy for selected x-ray field size over any SID.

Direct radiography via flat panel detector improves exam speed and comfort with efficiency. Digital flat panel detector with CsI screen provides spatial resolution, MTF, DQE and stability based on fine pixel pitch.

Selection of an anatomical study on the Digital Imaging Software automatically sets up the x-ray generator's pre-programmed exposure technique.

The types of "TOPAZ" system are divided into TOPAZ-32D, and TOPAZ-40D according to maximum power and mA. The higher the maximum output, the wider the mA range to choose from, giving the user more technical options to choose from.

- **Device Identification:**

The "TOPAZ Mobile X-ray System" consists of a tube assembly, x-ray collimator, High Voltage X-Ray Generator, detector and mechanical parts for mobility.

- **Device Characteristics:**

·Software

The subject device 'TOPAZ Mobile X-ray System' use software (including firmware).

Its S/W (RADMAX) can perform processing the radiological image acquired from Solid State X-ray Imaging Device.

Software being used is identical to the predicate device 'TOPAZ Mobile X-ray System', and its LOC (Level of Concern) is ' Basic Documentation Level'.

Accordingly, this software (RADMAX) is based on predicate device 'TOPAZ Mobile X-ray System'.

·Software Level Determination

Basic Documentation Level

The device does not contact the patient, nor does it control any life sustaining devices.
A physician, providing ample opportunity for competent human intervention, interprets all images and information being displayed and printed.

·**Cybersecurity**

This device complies with cybersecurity requirements by ensuring the confidentiality, integrity, and availability of data and systems.
Potential vulnerabilities were identified through cybersecurity risk analysis, which included threat modeling, risk assessment, and the development of a software bill of materials. The design integrates security controls, such as authentication, authorization, encryption, integrity verification, event detection and logging, retention, recovery and secure software updates. Verification and tests were conducted to ensure the effectiveness of the implemented cybersecurity controls. The product labeling includes cybersecurity-related information, and users are provided with guidance and training on instruction for use.

- **Environment of Use:**

This 'TOPAZ Mobile X-ray System' is for use by medical professional Facility.
To prevent excess radiation exposure to patient and operator from either primary or secondary radiation, this 'TOPAZ Mobile X-ray System' must be operated and serviced by trained personnel who are familiar with the safety precautions required.

- **Brief Written Description of the Device:**

The operating principles are as follows.
The irradiation conditions are 40 to 125 (150) kVp at the photographing site, and the tube current is 10 to 400 (500) mA. When X-rays generated under X-ray irradiation conditions enter the X-ray Film or Flat Panel detector, the film or flat panel detector detects X-rays incident through the incident surface during X-ray irradiation, and finally generates a radiographic image when X-ray irradiation is completed.

V. INDICATION FOR USE [21 CFR 807.92(a) (5)]

The 'TOPAZ Mobile X-ray System' is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis.

VI. TECHNOLOGICAL CHARACTERISTICS [21 CFR 807.92(a) (6)]

The Subject device 'TOPAZ Mobile X-ray System' (Model: TOPAZ-32D, TOPAZ-40D) is based on the Predicate Device (TOPAZ Mobile DR System, K201124) including the system control, Indication for use and mechanical design.

The differences between the subject device and the predicate device have been thoroughly tested and verified for safety and effectiveness by an accredited Safety and EMC testing laboratory.

This 510(k) submission describes some modifications to the previously cleared predicate devices the 'TOPAZ Mobile DR System' (K201124). The changes to the predicate 'TOPAZ Mobile DR System' (K201124) include:

Software update from TPZ_IWS 1.00.01 to RADMAX 1.02.09

1) Imaging Software Model Name Change: We have changed the model name of our imaging software from 'TPZ_IWS (XGRADMAX)' to 'RADMAX'.
2) Graphical user interface (GUI): GUI of system software updated in order to improve the look and feel of user interface for better visibility & faster workflow.
3) Image Processing Module added (Module 3, 4): We conducted performance verification of Flat Panel detectors compared to existing image processing modules. Verification and Validation testing concluded no impact on safety and effectiveness.

Component Change

1) 21.5” capacitive touch monitor is applied
   : 21.5" monitor is applied for improved viewing angle and wide screen.
2) New Collapsible Column Stand Option have been Added
   (Basic type, Collapsible type - Optional)
   : We have added a new Collapsible column type stand option to our product.
   This collapsible type column stand features a trendy design that allows driving without disturbing the front view.
3) Addition of detector : 4343W, Mars1417X, Mars1717X , Luna1012X, A1417MCW, A1717MCW, F1417MCW

·10x12 inch Wireless Flat Panel detectors have been added

·Luna1012X manufactured by IRAY Technology, FDA Cleared K221345

·14x17 inch Wireless Flat Panel detectors have been added

·Mars1417X manufactured by IRAY Technology, FDA Cleared K210316

·A1417MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930

·F1417MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930

·17x17 inch Wireless Flat Panel detectors have been added

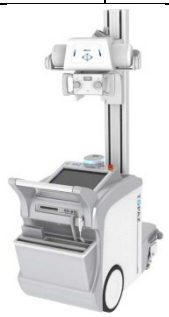
·4343W manufactured by Varex Imaging Corp, FDA Cleared K202572

·Mars1717X manufactured by IRAY Technology, FDA Cleared K210314

·A1717MCW manufactured by H&abyz Co., Ltd., FDA Cleared K223930

VII.SUBSTANTIAL EQUIVALENCE [21 CFR 807.92(b)]

Substantial Equivalence Comparison Table

Item	Subject Device		Predicate Device		Impact of Differences
Device Name	TOPAZ Mobile X-ray System		TOPAZ Mobile DR System		The TOPAZ Mobile DR System has been renamed to the TOPAZ Mobile X-ray System. This is a simple model name change, and the differences between the subject device and the predicate device do not affect the safety or efficacy of the modified device.
510(k) number	K242015		K202572		-
Manufacturer	DRGEM Corporation		DRGEM Corporation		-
Model Name	TOPAZ-32D	TOPAZ-40D	TOPAZ-32D	TOPAZ-40D	Same as predicate
Appearance	 Basic type Collapsible type				Yes, there is a difference Collapsible type Column Stand Option have been Added Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
Indications for Use	The ‘TOPAZ Mobile X-ray System’ is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis.		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.		Same as predicate The indications for use of the previous TOPAZ Mobile DR System and the current TOPAZ Mobile X-ray System is essentially the same. The previous device described the general intended use of acquiring X-ray images of the desired body part of the patient. The current device emphasizes the more specific situation of acquiring images of immobile patients. Therefore, the intended use of the two devices is essentially the same, with only differences in wording. This device is not intended for mammography, bone density, fluoroscopy and angiography applications. These contraindications apply to both the previous TOPAZ Mobile

					DR System and the current TOPAZ Mobile X-ray System. This matters are specified in the warning and contraindication sections on pages 13 and 18 of the Operation Manual (RMD1311-009)
1. High Frequency X- ray Generator					
Output Power Rating (kW)	32kW	40kW	32kW	40kW	Same as predicate
mA Range	Max. 400mA	Max. 500mA	Max. 400mA	Max. 500mA	
KV Range	40 ~125 kV (option: 150kV)	40 ~ 125 kV (option: 150kV)	40 ~125 kV (option: 150kV)	40 ~ 125 kV (option: 150kV)	
mAs Range	0.1 ~500mAs	0.1 ~500mAs	0.1 ~500mAs	0.1 ~500mAs	
2. X-ray tube housing Assembly					
Configuration model	E7239X / CANON		E7239X / CANON		Same as predicate
	E7242X / CANON		E7242X / CANON		
	E7299X / CANON		E7299X / CANON		
	E7876X / CANON		E7876X / CANON		
	E7884X / CANON		E7884X / CANON		
	DXT-8M / DRGEM		DXT-8M / DRGEM		
	DXT-11M / DRGEM		DXT-11M / DRGEM		
	DXT-10M / DRGEM		DXT-10M / DRGEM		
	DXT-12M / DRGEM		DXT-12M / DRGEM		
Focal spot	1.0/2.0mm, 0.3/1.0mm, 0.6/1.2mm, 0.6/1.5mm		1.0/2.0mm, 0.3/1.0mm, 0.6/1.2mm, 0.6/1.5mm		
Target angle	12° to 16 depending upon the Tube		12° to 16 depending upon the Tube		
Colum rotation range	± 325 degrees		± 325 degrees,		Yes, there is a difference. The addition of the Collapsible type Column Stand Option adds a 330 degree column rotation range. Models have been tested against International Safety and EMC Standards. Any differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
	± 330 degrees		-		
Tube (Arm axis)	± 180 degrees		± 180 degrees		Same as predicate
Tube axis rotation range	-30~+90 degrees		-30~+90 degrees		
Max Tube Voltage	125kV, 150kV		125kV, 150kV		
3. Collimator (Beam Limiting Device)					

Configuration model	R108/R108F	R108/R108F	Yes, there is a difference. Collimator Configuration Models have been partially deleted based on predicate device. It is our determination that there is “No negative impact on safety or effectiveness” and there are no new potential or increased safety risks concerning this difference
	DXC-RML	DXC-RML/DXC-RMH	
Lamp Type	LED lamp	LED and Halogen lamp	
4. Solid State X-ray Imaging Device			
Flat panel Detector	-	PaxScan4336W / VAREX	There are differences between the added detectors and the original detector used in the predicate device. All detectors have been tested for compatibility with TOPAZ via internal testing and the added detectors have been cleared by FDA 510(k)s. It is our determination that the added detectors do not have a negative impact on safety or efficacy and there are no new potential or increased safety risks concerning these differences.
	PaxScan4336W v4/ VAREX	PaxScan4336W v4/ VAREX	
	XRpad2 3025 HWC-M / VAREX	XRpad2 3025 HWC-M / VAREX	
	XRpad2 4336 HWC-M / VAREX	XRpad2 4336 HWC-M / VAREX	
	XRpad2 4343 HWC-M / VAREX	XRpad2 4343 HWC-M / VAREX	
	Mano4336W / IRAY	Mano4336W / IRAY	
	Mano4343W / IRAY	Mano4343W / IRAY	
	4343W / VAREX	-	
	Mars1417X / IRAY	-	
	Mars1717X / IRAY	-	
	Luna1012X / IRAY		
	F1417MCW / H&abyz	-	
	A1417MCW / H&abyz	-	
	A1717MCW / H&abyz	-	
5. Imaging Processing Software			
Configuration model	RADMAX	TPZ_IWS (XGRADMAX)	Yes, there is a difference. The model name has been changed.
Software Version	1.02 V	1.00 V	see below difference
Horizontal Flip	Yes	Yes	Yes
Vertical Flip	Yes	Yes	Yes
Rotate CW/CCW	Yes	Yes	Yes
Text Annotation	Yes	Yes	Yes
Ruler: Distance too	Yes	Yes	Yes
Angle measurement tool	Yes	Yes	Yes
Zoom	Yes	Yes	Yes
Magnify	Yes	Yes	Yes
Image panning	Yes	Yes	Yes
Auto fitting to window size	Yes	Yes	Yes
Image crop/cut	Yes	Yes	Yes
Image Copy	Yes	Yes	Yes
Recover the original image	Yes	Yes	Yes
Window level CD Burning	Yes	Yes	Yes
DICOM Print	Yes	Yes	Yes
Image Stitching	Yes	Yes	Yes
Image Processing Module	·Module 1 ·Module 2 ·Module 3	· Module1 : IMFOU · Module 2 : COV	Yes, there is a difference. Models have been conducted Verification activity. Any

	·Module 4		differences between the subject device and predicate device do not change or add new potential safety risks. It is our determination that there is "No negative impact on safety or effectiveness" and there are no new potential or increased safety risks concerning this difference
Specification	· MODULE 1 Edge Enhancement: 0 ~ 50 Contrast Factor : 1 ~ 200 Image Frequency : 0 ~ 20 Image Latitude : -10 ~ 10 Sharpness : 0 ~ 100 · MODULE 2 Histogram Optimization : -100 ~ 100 Skin line Weight : -100 ~ 100 Latitude Compression : -100 ~ 100 Contrast Enhancement : -100 ~ 100 Edge Enhancement : -100 ~ 100 Noise Suppression : -100 ~ 100 Gamma : -20 ~ 20 · MODULE 3 Global Brightness : -100 ~ 100 Global Contrast : -100 ~ 100 Latitude Compression : -100 ~ 100 S-Structure Enhancement : -100 ~ 100 Noise Suppression : -100 ~ 100 Gamma : -20 ~ 20 · MODULE 4 Global Brightness : -20 ~ 20 Global Contrast : -30 ~ 30 Local Contrast : 0 ~ 20 Small Enhancement : 0 ~ 20 Latitude Reduction : -20 ~ 20 Noise Suppression : 0 ~ 20 Gamma : -20 ~ 20	· Module1: IMFOU Edge Enhancement: 0 ~ 50 Contrast Factor : 1 ~ 200 Image Frequency : 0 ~ 20 Image Latitude : -10 ~ 10 Sharpness : 0 ~ 100 · Module 2 : COV Histogram Optimization : -1 ~ 1(0.01 Step) Skinline Weight : -1 ~ 1(0.01 Step) Latitude Compression : -1 ~ 1(0.01 Step) Contrast Enhancement : -1 ~ 1(0.01 Step) Edge Enhancement : -1 ~ 1(0.01 Step) Noise Suppression : -1 ~ 1(0.01 Step) Gamma : -20 ~ 20	

VIII. SUMMARY OF NON-CLINICAL Data [21 CFR 807.92(b) (1)]

Nonclinical Testing:
The 'TOPAZ Mobile X-ray 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.

Std	Safety/EMC Standards Description	FDA Rec. Standard
IEC 60601-1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-46
IEC 60601-1-2 (EMC)	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.	19-36
IEC 60601-1-3	Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	12-336
IEC 60601-1-6	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	5-132
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	12-309
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	12-348
IEC 62304:2006	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes	13-79
ISO 14971:2019	ISO 14971:2019 Third Edition, Medical devices - Applications of risk management to medical devices.	5-125
ISO 15223-1	ISO 15223-1 Fourth Edition 2021-07, Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.	5-134
NEMA PS 3.1 - 3.20 (2016).	NEMA PS 3.1 - 3.20 (2022). Digital Imaging and Communications in Medicine (DICOM) Set DICOM Standard.	12-349
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 (2005)	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

TR 60601-4-2	TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-19
FDA Guidance	Guidance for Industry and FDA Staff: Pediatric Information for X-ray Imaging Device Premarket Notifications dated November 28, 2017	
FDA Guidance	Format for Traditional and Abbreviated 510(k)s, Guidance for Industry and Food and Drug Administration Staff, Document issued on September 13, 2019.	
FDA Guidance	Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices dated September 1, 2016	
FDA Guidance	Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff Document issued on June 14, 2023.	
FDA Guidance	Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005	
FDA Guidance	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff Document issued on September 27, 2023.	

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 electrical safety, and EMC. 'TOPAZ Mobile X-ray System' has met all the requirements listed in the Standards except for inapplicable requirements (which are listed in the various test reports).

The subject device conforms to all applicable requirements of 21 CFR 1020.30-31

IX. CONCLUSIONS [21 CFR 807.92(b) (3)]

The 510(k) Pre-Market Notification for 'TOPAZ Mobile X-ray System', contains adequate information, data, and nonclinical test results to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device and the 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.