August 22, 2025

DRGEM Corporation
℅ Doonam Choi
Regulatory Affairs | Engineer
7F, E-B/D Gwangmyeong Techno-Park 60, Haan-ro
Gwangmyeong-si, Gyeonggi 14322
SOUTH KOREA

Re: K251443
Trade/Device Name: Promo
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: April 29, 2025
Received: July 22, 2025

Dear Doonam Choi:

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, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
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)*
K251443

Device Name
PROMO

Indications for Use *(Describe)*

The PROMO 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K251443

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

1. SUBMITTER

Manufacturer:	DRGEM Corporation
Address:	7F. E-B/D Gwangmyeong Techno-Park, 60 Haan-Ro Gwangmyeong-Si Gyeonggi, Republic of Korea, 14322
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Phone Number	+82-70-8230-8617
Fax Number	+82-2-869-8567
Date Prepared	December 27, 2024

2. PROPOSED DEVICE INFORMATION

Device Name:	PROMO
Classification Name:	Mobile X-ray System
Product Code:	IZL
Regulation Number:	892.1720
Associated Product Code:	MQB
Regulatory Class:	II

3. PREDICATE DEVICE INFORMATION

Device Name:	TOPAZ
Classification Name:	Mobile X-ray System
510(k) Number:	K242015
Product Code:	IZL
Regulation Number:	892.1720
Associated Product Code:	MQB
Regulatory Class:	II

4. DEVICE DESCRIPTION

The PROMO is based on predicate device TOPAZ and the x-ray detectors are the same as the predicate system.

- **Device Features:**

The PROMO is moved smoothly with manual by user.

The core part of x-ray source adopts high quality tube assembly, x-ray collimator, HV cable assembly and High Voltage x-ray Generator with excellent performance, lifetime and stability.

Digital flat panel detector with CsI screen provides excellent spatial resolution, MTF, DQE and stability based on fine pixel pitch.

The core part of x-ray source adopts high quality tube assembly, x-ray collimator, HV cable assembly and High Voltage x-ray Generator which have worldwide reputation on excellent performance, lifetime and stability. 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.

- **Device Characteristics:**

Software

The PROMO include imaging software that is the RADMAX.

The RADMAX software can perform processing the radiological image acquired from solid state x-ray imaging device.

The RADMAX software is based on predicate device TOPAZ.

The CTR function is a manual quantitative imaging feature that allows users to measure the cardiothoracic ratio by manually selecting points using a mouse. The software function has been verified and validated as safe and effective.

Software Level Determination

The RADMAX software is Basic Documentation Level.

This 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.

5. INDICATION FOR USE

The PROMO is intended for use in obtaining human anatomical images of patients who cannot be moved to the radiology department for medical diagnosis.

6. TECHNOLOGICAL CHARACTERISTICS

The PROMO is based on the predicate device TOPAZ (K242015) including the system control, Intended 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 (K242015).

For more detail, refer to the “Substantial Equivalence Comparison Table”

Substantial Equivalence Comparison Table

Item	Subject Device	Predicate Device	Impact of Differences
Regulation Description	System, X-ray, Mobile	System, X-ray, Mobile	Same
Product Code	IZL	IZL	Same
Regulation Number	892.1720	892.1720	Same
Associated Product Code	MQB	MQB	Same
Regulatory Class	II	II	Same
Appearance		 Basic type Collapsible type	It has been verified according to international safety and EMC standards, and the differences do not negatively impact safety or effectiveness.
Drive Type	Manual Driven	Electrical motor driven	It has been verified according to international safety and EMC standards, and the differences do not negatively impact safety or effectiveness.
Output Power Rating (kW)	40 kW	40 kW	Same
mA Range	10 ~ 500 mA	10 ~ 500 mA	
kV Range	40 ~ 125 kV	40 ~ 125 kV	
mAs Range	0.1 ~ 500 mAs	0.1 ~ 500 mAs	

X-ray tube model	LUC-12L	E7239X	It has been verified according to international safety and EMC standards, and the differences do not negatively impact safety or effectiveness.
		E7242X	
		E7299X	
		E7876X	
		E7884X	
		DXT-8M	
		DXT-11M	
		DXT-10M	
		DXT-12M	
Focal spot	0.6 mm / 1.5 mm	1.0 mm / 2.0 mm, 0.3 mm / 1.0 mm, 0.6 mm / 1.2 mm, 0.6 mm / 1.5 mm	
Target angle	14 °	12° ~ 16° depending upon the Tube	
Colum rotation range	0 ° (Fixed)	± 325 °	The rotation range is narrower compared to the predicate, but there is no negative impact on safety or effectiveness.
	Option : ±90 °	± 330 °	
Tube (Arm axis)	± 180 °	± 180 °	Same
Tube axis rotation range	-49° ~ +147 °	-30 °~+90 °	The rotation range has been extended, but there is no negative impact on safety or effectiveness.
Collimator	DXC-RML	DXC-RML	Same
Lamp Type	LED lamp	LED lamp	Same
DAP meter	120-131HS (RS485)	120-131HS (RS485)	Same
Detector	Mano4336W	Mano4336W	Same
	Mano4343W	Mano4343W	
	Mars1417X	Mars1417X	
	Mars1717X	Mars1717X	
Imaging software	RADMAX	RADMAX	Same
Display	21.5 inch touch screen	21.5 inch touch screen	Same

7. SUMMARY OF NON-CLINICAL Data

This 510(K) premarket notification includes non-clinical performance testing.

Tests were performed on the proposed PROMO according to the following FDA recognized standards and guidance document.

The verification and validation methods (test methods and acceptance criteria) used to evaluate the proposed PROMO is the same as those used for the predicate device TOPAZ (K242015) and follow International and FDA recognized consensus standards and guidance documents applicable to this device type.

Standards/ Guidance	Title
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-28 Edition 3.0 2017-06	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 Edition 2.0 2022-09	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
ISO 14971 Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
NEMA PS 3.1 - 3.20 2024e	Digital Imaging and Communications in Medicine (DICOM) Set
IEC 61910-1 Edition 1.0 2014-09	Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy
IEC TS 60601-4-2 Edition 1.0 2024-03	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
FDA Guidance	Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff, Document issued on November 28, 2017

FDA Guidance	Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices - Guidance for Industry and Food and Drug Administration Staff, Document issued on September 1, 2016
FDA Guidance	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] - Guidance for Industry and Food and Drug Administration Staff, Document issued on July 28, 2014
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	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

The subject mobile system PROMO is strongly based on the predicate TOPAZ. The x-ray exposure characteristics are the same and the flat-panel detectors are unchanged from the predicate. Bench testing was conducted to evaluate the image performance of the detector. The results showed that PROMO meets or exceeds TOPAZ in key image quality metrics such as uniformity, SNR, linearity, spatial resolution, and low contrast resolution. Therefore, the substantial equivalence in image quality performance is supported by objective bench testing data.

8. SUBSTANTIAL EQUIVALENCE CONCLUSION

The PROMO is substantially equivalent to the currently marketed and predicate device TOPAZ (K242015) in terms of the design features, technological characteristics, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance tests and testing as per FDA-recognized consensus standards. The test results demonstrate that the device conforms to its specifications and is safe and effective for its intended use.