May 14, 2026

DRGEM Corporation
% Yubin CHO
Regulatory Affairs / Associate Research Engineer
7f, E-B/D Gwangmyeong Techno-Park 60, Haan-Ro
Gwangmyeong-Si, Gyeonggi-do 14322
REPUBLIC OF KOREA

Re: K260085
Trade/Device Name: RAYMO Mobile X-ray System (Model: RAYMO)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: April 14, 2026
Received: April 14, 2026

Dear Yubin CHO:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260085

Device Name
RAYMO Mobile X-ray System (Model: RAYMO)

Indications for Use *(Describe)*
The 'RAYMO 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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DRGEM Corporation

510(k) Summary

K260085

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
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Date Prepared:	January 9, 2026

2. PROPOSED DEVICE INFORMATION

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

- **Device Feature**

RAYMO Mobile X-ray System

"RAYMO" system is a system providing state-of-the-art image quality, user interface; making the system easy to use and reliable while providing high quality radiographic images.

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

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.

Direct radiography via flat panel detector improves workflow, exam speed and comfort with efficiency. 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, motorized 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 Tube Head Unit (THU) provides user-friendly interface and easy technique selection. 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.

Additionally, "RADMAX M" software for Smart Devices connects wirelessly to the RADMAX program on the workstation, providing various functions such as system status monitoring, worklists, and procedures.

- **Device Identification**

The "RAYMO 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
This device 'RAYMO Mobile X-ray System' use software including firmware.
The "RADMAX" software can perform processing the radiological image acquired from Solid State X-ray Imaging Device.
"RADMAX" 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 "RADMAX" software is based on predicate device 'RAYMO Mobile X-ray System'.

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.

- **Environment of Use**

This 'RAYMO 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 'RAYMO 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.

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

The 'RAYMO 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.

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

This device 'RAYMO Mobile X-ray System' is based on the Predicate Device "TOPAZ Mobile X-ray System" (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 Mobile X-ray System" (K242015).

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

Item	Subject Device (Model: RAYMO)	Predicate Device (TOPAZ - 40D)	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
Indications for Use	The 'RAYMO 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 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	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	Electrical motor driven	Electrical motor driven	Same
1. High Frequency X-ray Generator			
Output Power Rating (kW)	40 kW	40 kW	Same
mA Range	Max. 500 mA	Max. 500 mA	
kV Range	40 ~ 125 kV (Option: 150Kv)	40 ~ 125 kV (Option: 150Kv)	
mAs Range	0.1 ~ 500 mAs	0.1 ~500 mAs	
2. X-ray tube Assembly and tube support			
X-ray tube model	DXT-11L / DXT-13L	E7239X	It has been verified according to international safety and EMC standards, and the differences do not negatively impact safety or
		E7242X	
		E7299X	
		E7876X	
		E7884X	

Item	Subject Device (Model: RAYMO)	Predicate Device (TOPAZ - 40D)	Impact of Differences
		DXT-8M	effectiveness.
		DXT-11M	
		DXT-10M	
		DXT-12M	
Focal spot	0.6 mm/ 1.5 mm 0.6 mm/ 1.2 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° to 16° depending upon the Tube	
Colum rotation range	± 330 °	± 325 °(Option: ± 330 °)	The rotation range is narrower compared to the predicate, but there is no negative impact on safety or effectiveness.
Tube (Arm axis)	± 180 °	± 180 °	Same
Tube axis rotation range	-30 ° ~ +90 °	-30 ° ~ +90 °	Same
2. X-ray Collimator			
Collimator	Auto Collimator	DXC-RML	It has been verified according to international safety and EMC standards, and the differences do not negatively impact safety or effectiveness.
Lamp Type	LED lamp	LED lamp	Same
3. THU			
Display Type	10.1 inch Touch Screen	-	The THU incorporated in RAYMO serves solely as a user interface (UI) enhancement for operational convenience and does not have an impact on the device's essential performance, including X-ray generation, radiation dose control, or radiation output
Software/ Firmware	THU Main Board	-	
3. Solid State X-ray Imaging Device			
Flat Panel Detector	PaxScan4336W v4	PaxScan4336W v4	Same
	Mano4336W	Mano4336W	
	Mano4343W	Mano4343W	
	4343W	4343W	

Item	Subject Device (Model: RAYMO)	Predicate Device (TOPAZ - 40D)	Impact of Differences
	Mars1417X	Mars1417X	
	Mars1717X	Mars1717X	
	Luna1012X	Luna1012X	
	F1417MCW	F1417MCW	
	A1417MCW	A1417MCW	
	A1717MCW	A1717MCW	
4. Software			
Operating Software	RADMAX	RADMAX	Same
Smart Device SW	RADMAX M	-	RADMAX M software exchanges data with the RADMAX workstation ("RADMAX") and serves as a helpful auxiliary tool that supports workflow and system monitoring, even when the system is located at a physical distance.

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

Nonclinical Testing:
The 'RAYMO 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	Description	FDA Rec. Standard
IEC60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-49
IEC60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance	19-36
IEC60601-1-3	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance	12-336
IEC60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance	5-132
IEC60601-2-28	Medical electrical equipment - Part 2-28: Particular requirements for basic safety and essential performance	12-309
IEC60601-2-54	Medical electrical equipment - Part 2-54: Particular requirements for basic safety and essential performance	12-348

Std	Description	FDA Rec. Standard
IEC62304	Medical device software - Software life cycle processes	13-79
NEMA PS3.1 - 3.20 2023e	Digital Imaging and Communications in Medicine (DICOM) Set	12-352
ISOIEC10918-1	Information technology - Digital compression and coding of continuous-tone still images: Requirements and guidelines	12-261
IEC62494-1	Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography	12-215
ISO14971	Medical devices - Application of risk management to medical devices	5-125
ISO15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
IEC62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
IEC TR60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-50

Guidance documents
Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff, Document issued on November 28, 2017
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
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions- Guidance for Industry and Food and Drug Administration Staff, Document issued on February 3, 2026
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
Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff, Document issued on June 14, 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. 'RAYMO 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

9. SUMMARY OF CLINICAL Data [21 CFR 807.92(b) (2)]

① Description of Subjects Tested

A comparative clinical image assessment was conducted using 30 paired examinations obtained from adult inpatients during the period from December 26, 2025 to March 27, 2026. Images were acquired from both the subject device (RAYMO) and the predicate device (TOPAZ) within the same institutional environment, minimizing variability associated with differences in imaging conditions.

② Safety and Effectiveness Data

The average quality score of the 30 pairs of examination images exceeded the predefined acceptance threshold of 60 points for both devices, confirming clinically acceptable diagnostic image quality.
Entrance Surface Dose (ESD) assessment did not reveal any clinically meaningful radiation safety concern.
No adverse effects or complications were identified in association with the use of the subject device.

③ Conclusions Relevant to Substantial Equivalence

The comparative assessment demonstrated that the RAYMO Mobile X-ray System provides clinically acceptable image quality comparable to that of the predicate device, TOPAZ. The identified differences between the subject device and the predicate device did not adversely affect safety, effectiveness, or substantial equivalence.

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

The 510(k) Pre-Market Notification for the ‘RAYMO Mobile X-ray System’ contains adequate information, data, and nonclinical and clinical 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. The intended use of the subject device does not raise any new potential safety risks, and the device is equivalent in performance to the existing legally marketed device.
Nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs comparably to the predicate devices.