July 31, 2025

REMEDI Inc.
℅ Seong-Geun Park
Regulatory Manager
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SEOUL, 072NN
SOUTH KOREA

Re: K250597
Trade/Device Name: REMEX Xcam6
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: December 20, 2024
Received: July 2, 2025

Dear Seong-Geun Park:

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

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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Office of Product Evaluation and Quality
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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)*
K250597

Device Name
REMEX Xcam6

Indications for Use *(Describe)*

Portable X-ray Equipment REMEX Xcam6 is intended to be used in a hospital or clinic setting under the supervision of a qualified and trained clinician. This product is used as an x-ray source to produce diagnostic x-ray images of patient's extremities using an X-ray detector. It may be used in handheld or stand-mounted configurations for acquiring diagnostic radiographic images of extremities.

The device is not intended for mammography.
The REMEX Xcam6 is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

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: K250597

I. SUBMITTER

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II. DEVICE

Name: REMEX Xcam6
Common Name: System, X-Ray, Mobile
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Product Code: IZL
Regulatory Class: II

III. PREDICATE DEVICE

Manufacturer: MinXray, Inc. (Northbrook, IL, USA)
Name: TR90BH
Common name: System, X-Ray, Mobile
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Product Code: IZL
Regulatory Class: II
510(k) Number: K182207

IV. DEVICE DESCRIPTION

The REMEX Xcam6 is a handheld and portable general-purpose X-ray system intended for use by qualified and trained clinicians to obtain diagnostic radiographic images of patient's extremities.
The REMEX Xcam6 serves as an X-ray source and is designed to be used in conjunction with a Flat Panel Detector (FPD), which is not included as part of the system. The FPD is connected to a computer equipped with imaging software that enables image acquisition, display, manipulation, storage, and transmission.
The X-ray source is securely enclosed within the housing of the handheld unit, and the device does not come into direct contact with the patient during use.
During imaging procedures, the patient is positioned appropriately—either sitting or lying down—and the X-ray receptor is aligned accordingly. The patient is instructed to remain still while the operator sets the exposure parameters and initiates the radiographic exposure.
The operator has control over the following exposure parameters:

1. Tube Voltage (kVp): Adjustable from 40 to 90 kVp, in 1 kV increments.
2. Tube Current (mA): Adjustable from 2 to 6 mA, in 1 mA increments.
3. Exposure Time: Adjustable from 0.06 to 2.00 seconds, in 0.01-second increments.

V. INDICATIONS FOR USE

Portable X-ray Equipment REMEX Xcam6 is intended to be used in a hospital or clinic setting under the supervision of a qualified and trained clinician. This product is used as an x-ray source to produce diagnostic x-ray images of patient's extremities using an X-ray detector. It may be used in handheld or stand-mounted configurations for acquiring diagnostic radiographic images of extremities.

The device is not intended for mammography.
The REMEX Xcam6 is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table compares technological and other characteristics of the subject and predicate devices.

	REMEX-Xcam6 (Subject Device)	**TR90BH (K182207)**	**Comparison**
Classification & Product code	892.1720; IZL	892.1720; IZL	Same
Intended Use	Portable X-ray Equipment REMEX Xcam6 is intended to be used in a hospital or clinic setting	The TR90BH is a portable X-ray system with following limitations of use:	Similar

	REMEX-Xcam6 (Subject Device)	TR90BH (K182207)	Comparison
	under the supervision of a qualified and trained clinician. This product is used as an x-ray source to produce diagnostic x-ray images of patient's extremities using an X-ray detector. It may be used in handheld or stand-mounted configurations for acquiring diagnostic radiographic images of extremities. The device is not intended for mammography. The REMEX Xcam6 is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	The device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities - Not for mammography use - The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	
Size: Body	165.3 x 176 x 335.6 mm	219 x 442 x 190 mm	Different
Weight	2.4 kg (including Cone 190g)	7.7 kgs (With Battery)	Different
Energy Source	Lithium-polymer Rechargeable Battery, 22.2Vdc, 1800mAh	Lithium-ion Rechargeable Battery, 57.6 Vdc, 1900mAh	Different
User Interface	Up-Down pushbuttons for selection of exposure time, kV, and mA.	Up-Down pushbuttons for selection of exposure time, kV, and mA.	Same
Total Filtration	3.6mm Al	Minimum 3.0mm Al	Similar
Exposure times	0.06 -2.0 sec (0.01 sec. steps)	0.01 sec – 1.0 sec: 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec: 0.01 sec Step	Different
Tube voltage	40 - 90 kV (1 kV steps)	40 – 90 kVp (2 kV steps)	Similar
Tube Current (mA)	2 ~ 6 mA @ 40 to 80 kV 2 ~ 5 mA @ 81 to 90 kV	20 mA@40-60 kVDC 15 mA@62-80 kVDC 10 mA @82-90 kVDC 15mA@82-90 kVDC in High Power Mode(2kVp steps)	Different
Maximum Output(mAs)	12 mAs @ 40 to 80 kV 10 mAs @ 81 to 90 kV	20 mAs@40-60 kV 15 mAs@62-80 kV 3 mAs @82-90 kV 4.5 mAs@82-90 kVDC in High Power Mode	Simillar at low kVp Different at high kVp

	REMEX-Xcam6 (Subject Device)	TR90BH (K182207)	Comparison
Source to Skin Distance (SSD)	300 mm	300 mm	Same
Maximum symmetrical Radiation Field	430.0 mm X 430.0 mm at SID 1,000 mm	44cm X 44cm @SID 100cm	Similar
Accuracy of loading factor	Tube voltage: less than 10% Tube current: less than 20% Time: less than +/-(10%+1ms)	Tube voltage: +/-10% Tube current: +/-20% Time: +/-(10%+1ms)	Same
X-ray tube	Canon D-041SB with Modification	Canon D-0814M	Different
Focal Spot Size	0.4mm	0.8mm	Different
Performance Standard	IEC 60601-1:2020 IEC 60601-1-2:2020 IEC 60601-1-3:2021 IEC 60601-1-6:2021 IEC 60601-2-28:2017 IEC 60601-2-54:2022 IEC 62304:2015 IEC 62366-1:2020	IEC 60601-1:2012 IEC 60601-1-2:2007 IEC 60601-1-3:2008 IEC 60601-1-6:2010 IEC 60601-2-28:2010 IEC 60601-2-54:2009 IEC 62304:2006 IEC 62366-1:2014	Similar
Compatible X-ray Detector	Trade/Device name: PIXX 1717 Manufacturer: PIXXGEN Corporation 510(k) Number: K180976	-	-

The predicate device, TR90BH, is intended for acquiring X-ray images of the patient's head, abdomen, chest, and extremities, whereas the REMEX Xcam6 is intended for diagnostic imaging of body extremities only. This difference does not materially alter the primary intended use, which is the acquisition of diagnostic X-ray images of extremities.

The REMEX Xcam6 differs from the predicate device in certain design aspects, including physical dimensions, weight, power source, and X-ray tube configuration. These differences reflect design optimizations to enhance portability and do not introduce new questions of safety or effectiveness. Although there are differences in tube current range and exposure time between the two devices, these parameters have been fully validated through bench testing and clinical image evaluations. The REMEX Xcam6 has also undergone testing and verification for electrical safety, electromagnetic compatibility (EMC), and software performance in accordance with applicable standards.

The results of these evaluations demonstrate that the REMEX Xcam6 is as safe and effective as the predicate device and support a determination of substantial equivalence.

VII. Summary of Clinical and Non-clinical testing

To establish substantial equivalence, both non-clinical and clinical performance testing were conducted on the REMEX Xcam6. The testing demonstrated that the subject device is as safe and effective as the predicate device and performs as intended.

A summary of the standards followed is provided below:

Standard	Contents	FDA Rec. standard
ISO 14971:2019	Medical devices - Application of risk management to medical devices	5-125
IEC 60601-1:2005/A2:2020	Medical electrical equipment Part 1: General requirement for basic safety and essential performance	19-49
IEC 60601-1-2:2014/A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36
IEC 60601-1-3:2008/A2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	12-336
IEC 60601-1-6:2010/A2:2020	Medical electrical equipment Part 1-6: General requirements for safety – Collateral standard: Usability	5-132
IEC 60601-2-28:2017	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	12-309
IEC 60601-2-54:2022	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	12-348
IEC 62366-1:2015/A1:2020	Medical devices. Application of usability engineering to medical devices.	5-129
IEC 62304:2006/A1:2015	Medical device software - Software life-cycle processes	13-79
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
21 CFR 1020.30	Diagnostic x-ray system and their major components	
21 CFR 1020.31	Radiographic equipment	

- **Electrical safety and electromagnetic compatibility (EMC)**

  Electrical safety and electromagnetic compatibility (EMC) testing were conducted in accordance with applicable international and FDA-recognized standards. The REMEX Xcam6

complies with the IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-54 standard for safety and IEC 60601-1-2 standard for EMC.

- **Image quality and dosimetry bench testing**

  Bench testing was performed to evaluate image quality and dosimetry using phantoms. The device met all predefined acceptance criteria established in the test protocol. The results confirm that the image quality and radiation dose characteristics of the subject device are substantially equivalent to those of the predicate device.

- **Software Verification and Validation Testing**

  Software verification and validation were performed in accordance with IEC 62304:2006/A1:2015, Medical device software – Software life cycle processes. The REMEX Xcam6 software is classified as Class B under IEC 62304, indicating that a software failure or latent defect could pose a low level of risk, potentially resulting in non-serious injury to the patient, operator, or others. Cybersecurity was addressed per FDA guidance, " Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions ".

- **Clinical Performance Testing**

  A limited clinical test was conducted to confirm the device's capability to produce diagnostic images of body extremities. The acquired images were reviewed and assessed by a board-certified radiologist, who verified that the device performed successfully and that the image quality was suitable for diagnostic interpretation.

VIII. CONCLUSIONS

A comparison of the intended use and technological characteristics demonstrates that the REMEX Xcam6 is at least as safe and effective as the predicate device. The analysis supports a determination of substantial equivalence between the subject device and the predicate. Performance data, including bench testing and clinical image evaluations, further support the safety and effectiveness of the REMEX Xcam6. These results confirm that the device performs as intended under the specified use conditions.

Accordingly, the REMEX Xcam6 is considered substantially equivalent to the predicate device, in accordance with the criteria outlined in 21 CFR § 807.92.