Remedi Co. Ltd.
% Mr. W. Lee Strong
Quality Systems Manager
510K FDA, Inc.
100 E Granada Blvd, Suite 219
ORMOND BEACH FL 32176

August 3, 2021

Re: K212144
Trade/Device Name: Remex KA6
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: July 6, 2021
Received: July 9, 2021

Dear Mr. Strong:

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/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 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 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212144

Device Name
REMEX KA6

Indications for Use *(Describe)*
The KA6 is a portable X-ray system for diagnostic imaging of body extremities.

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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510k FDA Consulting

Medical Device Clearance

100 East Granada Blvd., Suite 219 Ormond Beach, FL 32176 386-506-8711

510(k) Summary

K212144

Submitter

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Primary Contact: W. Lee Strong, Quality Systems Manager ()
Secondary Contact: Claude Berthoin, President (Claude@510kfda.com)

Device Classification

Trade Names:	Remex KA6
Common Name:	Mobile X-Ray System
Regulation Name:	Mobile X-Ray System
Regulation Number:	21 CFR 892.1720
Medical Specialty:	Radiology
Regulatory Class:	II
Product Code:	IZL
Submission Type:	510(k)
Regulatory Class:	2

Predicate Devices

The following predicates are legally marketed, post-amendment devices:

510(k) Number:	K182207
Clearance Date:	December 14, 2018
510(k) Trade Name:	MinXray TR90BH
Submitters:	Mikasa X-Ray Co., Ltd. (Tokyo, Japan)
	MinXray, Inc. (Northbrook, Illinois, USA)
Regulatory Class:	II
Regulation Number:	21 CFR 892.1720
Regulation Name:	Mobile X-Ray System
Product Code:	IZL

Device Description

The **Remex KA6** is a handheld battery-operated x-ray system intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

The subject device is designed as an x-ray source to take diagnostic x-rays as radiographic images. The x-ray tube by Canon (tube voltage 40-70kV with 0.4 mm focal spot) is located inside the handheld device. The device is used with a Flat Panel X-ray Detector(FXRD), not part of the system, which is attached to a computer with imaging software to enable image capture, display, manipulation, storage, and transmission. The device is not designed to be used with a radiographic grid.

The operator controls three key variables to obtain the best image at minimal exposure:

1. X-Ray Exposure Intensity can be changed from 40 kV to 70 kV in 1 kV increments.
2. X-Ray Exposure Dosage can be changed from 2mA – 6mA in 1mA increments.
3. X-Ray Exposure Time can be changed from 0.06 sec – 2.00 sec in 0.01 increments.

Indications for Use

The KA6 is a handheld portable X-ray system for diagnostic imaging of body extremities.

The device was previously submitted to the FDA in submission number K202559 and found not-substantially equivalent (NSE). The Remex KA6 is being re-submitted with an adjusted IFU statement.

Comparison of Technological Characteristics with Predicates

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

Characteristic	Remex KA6 (K212144)	MinXray TR90BH (K182207)
Intended Use	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.
Indications for Use	The KA6 is a portable X-ray system for diagnostic imaging of body extremities.	The TR90BH is a portable X-ray system with following limitations of use: 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.
Comment on Indications	Certain limitations apply because of the lower maximum kVp output as compared to the predicate. See indications above.	Original Indications

Characteristic	Remex KA6 (K212144)	MinXray TR90BH (K182207)
Size: Body	165 x 176 x 255 mm	219 x 442 x 190 mm
Weight	2.4 kg (including cone 190g)	7.5kg
Energy Source	Lithium Polymer Rechargeable Battery (22.2 VDC), 300 exposures per charge	Lithium-ion Rechargeable Battery (57.6 VDC), 300 exposures per charge.
Mounting method	Unit is usually handheld, or mounted on optional arms or tripod	Unit is usually mounted to a MinXray XGS MKIII Portable Stand
User Interface	Up-Down pushbuttons for selection of exposure time, kVp, and mA, with LED indicators	Up-Down pushbuttons for kVp selections and exposure time selections with LED indicators
Exposure switch	Dual-stage, deadman type	Dual-stage, deadman type
Controls	Built-in Software - S/W name: RPG-F-0706 - S/W version: 1.00	Analog/digital, no software
Exposure times	0.06 -2.0 sec (0.01 sec. steps)	0.03-0.2 sec (0.01 sec. Steps) 0.2-04 sec (0.02 sec. Steps) 04-1.0 sec (0.05 sec. Steps) 1.0-4.0 sec (0.1 sec. Steps)
Tube potential (kVp)	40 - 70 kVp (1 kVp steps)	40 – 90 kVp

Characteristic	Remex KA6 (K212144)	MinXray TR90BH (K182207)
Tube current (mA)	2 mA - 6 mA (1 mA steps)	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps)
Alerts and Alarms	At least three specific alerts and alarms indicate equipment state of readiness to use.	At least two specific alerts and alarms indicate equipment state of readiness to use.
X-ray tube	Canon D-041SB	Toshiba D-0814
Focal Spot Size	0.4 mm	1.2 mm
Total filtration	1.6 mm Al equivalent	3.2mm AL equivalent
Collimator	Square collimator with LED Light Field Center Indicator	Four manually and steplessly adjustable shutters with light beam type central x-ray indicator (Advantech R72)
Triggering Mechanism	Two stage triggering	Two stage triggering
Source to Skin Distance (SSD)	300 mm	300 mm
Performance Standard	IEC 60601-1-3:2013 IEC 60601-2-28:2017 IEC 60601-2-54:2009	IEC 60601-1-3:2008 IEC 60601-1-2-28:2010 IEC 60601-2-54:2009

Characteristic	Remex KA6 (K212144)	MinXray TR90BH (K182207)
Electrical safety	IEC 60601-1:2012	IEC 60601-1:2012
	IEC 60601-1-2:2014	IEC 60601-1-2:2007
	IEC 60601-1-6:2013	IEC 60601-1-6:2010
	IEC 62304:2006	IEC 62304:2006
	IEC 62366:2007	IEC 62366:2007

Both the subject Remex KA6 and predicate MinXray TR90BH device are intended for mobile x-ray examination of adult and pediatric populations.

The subject device is lightweight and designed for handheld use and transport in a carry case, while the predicates are heavy enough to generally require mounting and transport on a portable stand.

The subject is DC-powered by battery, while the predicate is AC-powered via wall outlet. Both the subject and predicates are operated by push buttons and/or touch screen on the device itself.

The above comparison of technological characteristics shows the Remex KA6 to be smaller, lighter, and less powerful than the predicate, with lower tube voltage and current being the more obvious examples. These variations raise no new issues of safety or effectiveness.

Performance Data

The following performance data were provided in support of the substantial equivalence determination…

1. Software – Remex KA6 completed software validation and was determined to be a moderate level of concern software. The risk management test was performed in accordance with ISO 14971 and met all requirements of the standard. These tests were performed by the manufacturer and all requirements were met.

2. Electrical Safety –Accredited Testing Laboratory KCTL Inc. performed tests for 60601-1, 60601-1-3, 60601-1-6, and 60601-2-28, and 60601-2-54 and met all requirements for electrical safety.

3. Electromagnetic Compatibility (EMC)—KCTL performed tests for 60601-1-2and met all requirements for safety.

4. Bench Testing – Performance tests for radiation protection in x-ray equipment was completed by an outside laborabory, KCTL, and met the test requirements.

5. Clinical Evaluation - Images from the Remex KA6 were evaluated for diagnostic quality by a board certified radiologist and were approved for diagnostic quality.

Risk Analysis Information

Risks associated with the handheld design include increased operator exposure due to leakage radiation and backscatter radiation. Methods to reduce exposure include proper lead lining around the x-ray source assembly, measurement of a typical exposure near and around the unit, and recommended safety precautions such as wearing personnel monitoring and protective equipment.

NOTE: The use of a tripod stand is recommended if you need the device to be more stable while taking the images to prevent blurry imaging. This is an accessory to the Remex KA6.

The Remex KA6 has a Source-Skin Distance (SSD) cage that is attached to the device to maintain a minimum SSD of 300 mm. Operators are not to remove this cage to bring the device closer to the patient. Images may be taken at a distance greater than the cage to the source, but cannot be taken closer than the cage allows.

The petition was prepared in compliances with the following FDA guidance instructions and documents: "*FDA Guidance on Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use."*

Conclusions

The comparison of intended use and technological characteristics shows the subject device to be **at least as safe and effective as** the predicate, and, furthermore, warrants a finding of **substantial equivalence** between the Remex KA6 and MinXray TR90BH predicate.

The non-clinical data support the safety of the device and demonstrate that Remex KA6 should perform as intended in the specified use conditions.

Clinical images from the Remex KA6 were evaluated for diagnostic quality by a board certified radiologist and were approved for diagnostic quality.