July 29, 2025

Prognosys Medical Systems Private Limited
℅ Ankur Naik
Managing Director
IZiel Healthcare
Pentagon P1, Office No. 601 and 604, Magarpatta City,
Hadapsar
Pune, Maharashtra 411028
INDIA

Re: K243473
Trade/Device Name: Prorad Atlas Ultraportable
Prorad Atlas Ultraportable Plus
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: June 26, 2025
Received: June 26, 2025

Dear Ankur Naik:

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
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)*
K243473

Device Name
PRORAD ATLAS ULTRAPORTABLE
PRORAD ATLAS ULTRAPORTABLE PLUS

Indications for Use *(Describe)*
The PRORAD ATLAS ULTRAPORTABLE Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray unit, flat-panel detector and image acquisition software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted.
The PRORAD ATLAS ULTRAPORTABLE X-ray digital system is predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established, especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas.
The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.

The PRORAD ATLAS ULTRAPORTABLE PLUS Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray Unit, flat-panel detector and real-time image processing using software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted.
The PRORAD ATLAS ULTRAPORTABLE PLUS X-ray digital system is predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established, especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas.
The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.

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.

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510(k) Summary

510(k) summary of safety and effectiveness for PRORAD ATLAS X-Ray system is provided in accordance with 21 CFR 807.92.

Date:	29 July 2025
Submitter (Owner):	Krishna Prasad Vajapeyam Founder and President Prognosys Medical Systems Private Limited. #168/1, Machohalli, Dasanapura Hobli, next to Vani Vidhyalaya, Off. Magadi Road, Bangalore - 560 091, India P: +91 9845290091 Email: krishna.prasad@prognosysmedical.com
510(k) Contact Person:	Ankur Naik Managing Director IZiel Healthcare Pentagon P1, Office No. 601 and 604, Magarpatta City, Hadapsar, Pune 411028, Maharashtra, India P: +91 72762 2555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	PRORAD ATLAS ULTRAPORTABLE PRORAD ATLAS ULTRAPORTABLE PLUS
Regulation Number:	21 CFR 892.1720
Review Panel:	Radiology
Device Class:	Class II
Product Code:	IZL
Predicate Device:	Remex KA6 (K212144)

Device Description

The PRORAD ATLAS X-Ray system includes the ULTRAPORTABLE and ULTRAPORTABLE PLUS, which are portable diagnostic X-ray systems with fixed 70kV and 2mA tube current. These systems are intended to produce anatomical X-rays of the body extremities in both pediatric and adult patients. The PRORAD ATLAS X-Ray system was designed, developed, and manufactured by Prognosys Medical Systems Private Limited. The model numbers are listed below.

Model Number	Model Name	Model Description
A86-ATL-0001	PRORAD ATLAS ULTRAPORTABLE	These are ultraportable X-ray systems designed to generate diagnostic, high-quality X-ray images
A87-ATL-0001	The PRORAD ATLAS ULTRAPORTABLE PLUS	

The PRORAD ATLAS X-ray system is a sophisticated, battery-powered X-ray generator offered in two versions: PRORAD ATLAS ULTRAPORTABLE and ULTRAPORTABLE PLUS. The main distinction between these models lies in their exposure time ranges and target anatomical areas. The ULTRAPORTABLE model provides exposure times ranging from 0.01 to 1.30 seconds, while the ULTRAPORTABLE PLUS model offers an extended exposure range of 0.01 to 2.5 seconds. Both models share identical internal components, software, algorithms, and operational features and are intended for imaging body extremities. The system includes a high-voltage tank with an X-ray tube mounted on an adjustable tripod stand, allowing users to adjust the height to the specific imaging area. Exposure parameters are configured through the X-ray generator's graphical user interface (GUI). After setting the parameters and positioning the patient on the detector, the X-ray is activated via an exposure switch. The detector captures the radiation, converts it into a digital signal, and transmits the data wirelessly to a computer equipped with compatible software. The images are processed and displayed on the computer for diagnostic review. The PRORAD ATLAS system is compatible with several 510(k)-cleared detectors and their associated software, listed below in Table 1. Prognosys includes one detector and its pre-configured software in the package, depending on availability. Fully battery-operated, the system does not support direct power connection but can seamlessly integrate with multiple detectors and compatible software as part of the package.

Table 1: List of flat-panel detectors and compatible software

S. no	Flat panel Detectors	Software	Manufacturer/Supplier Name	510(k) Number
1.	Yushan X-ray Flat Panel detector with DROC Model name: V17Ce	DROC	InnoCare Optoelectronics Corp.	K220510
2.	Yushan X-ray Flat Panel detector with DROC Model name: F14C, F14G	DROC	InnoCare Optoelectronics Corp.	K210988
3.	Yushan X-ray Flat Panel detector with DROC Model Name: V14C, V14G, V17C, V17G, V17Ge	DROC	InnoCare Optoelectronics Corp.	K201528
4.	DIGITAL RADIOGRAPHY	CXDI Control Software	Canon Inc.	K213780

S. no	Flat panel Detectors	Software	Manufacturer/Supplier Name	510(k) Number
	CXDI-710C Wireless			
5.	DIGITAL RADIOGRAPHY CXDI-CS01	CXDI Control Software	Canon Inc.	K230175
6.	Flat panel Digital X-ray detector 14HQ721G-B	14HQ721G-B Software	LG Electronics Inc.	K221394
7.	Flat panel Digital X-ray Detector 17HQ901G-B	17HQ901G-B Software	LG Electronics Inc.	K214044
8.	Flat panel Digital X-ray Detector 14HK701G-W	14HK701G-W Software	LG Electronics Inc.	K182348
9.	Mars1717X Wireless Digital Flat Panel Detector Mars1717X	iRay SDK	iRay Technology Taicang Ltd.	K210314
10.	Wireless Digital Flat Panel Detector Mars1417X	iRay SDK	iRay Technology Taicang Ltd.	K210316
11.	Nexus DR ™ Digital X-ray Imaging System (with PaxScan 4343RC and PaxScan 4343Rv3)	Nexus DR ™ Digital X-ray Imaging System -Digital Imaging software	Varex Imaging Corporation	K172951
12.	XRpad2 4343 HWC-M Flat Panel Detector	XRpad2 4343 HWC-M Flat Panel Detector	Varex Imaging Corporation	K181526
13	PRORAD X-ray Flat Panel detector with DROC Model Name: V14 Clarity ,V14 HC ,V17 Clarity ,V17 HC,W17 HC ,W17 Clarity ,F14 Clarity ,F14 HC	DROC	PRORAD.	K240771

Intended Use / Indications for Use

PRORAD ATLAS ULTRAPORTABLE

The PRORAD ATLAS ULTRAPORTABLE Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray unit, flat-panel detector and image acquisition software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted.

The PRORAD ATLAS ULTRAPORTABLE X-ray digital system is predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established, especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas.

The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.

PRORAD ATLAS ULTRAPORTABLE PLUS

The PRORAD ATLAS ULTRAPORTABLE PLUS Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray Unit, flat-panel detector and real-time image processing using software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted.

The PRORAD ATLAS ULTRAPORTABLE PLUS X-ray digital system is predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established, especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas.

The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.

Substantial Equivalence Discussion

Remex KA6 (K212144) has been selected as the primary predicate device for the substantial equivalence discussion for PRORAD ATLAS X-Ray System. The details regarding the substantial equivalence between the subject device and the predicate device are explained below:

Technological Characteristics Comparison

Table 2: Technological Characteristics Comparison

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
Product Name	PRORAD ATLAS X-Ray System	Remex KA6	Not applicable
Manufacturer	Prognosys Medical Systems Private Limited	Remedi Co., Ltd.	Not applicable
Regulation Number	21 CFR 892.1720	21 CFR 892.1720	Identical
Product Code	IZL	IZL	Identical
Product Class	II	II	Identical
Indication for Use	The PRORAD ATLAS ULTRAPORTABLE Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray unit, flat-panel detector and image acquisition software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted. The PRORAD ATLAS ULTRAPORTABLE X-ray digital system is predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established,	The KA6 is a handheld portable X-ray system for diagnostic imaging of body extremities.	Identical The indications for use statement of the subject device is elaborated to include the use environment and the primary users of the device. The intended use of both the subject device and the predicate device remains the same and this is demonstrated through the various testing data conducted to support the safety and performance of the subject device.

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
	especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas. The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.		
	The PRORAD ATLAS ULTRAPORTABLE PLUS Digital X-ray system is intended to deliver high-quality, diagnostic radiographic images of the body extremities. It utilizes a portable X-ray Unit, flat-panel detector and real-time image processing using software to produce clear digital images, enabling fast and accurate diagnosis. The portable X-ray unit is intended to be used only when stand/tripod mounted. The PRORAD ATLAS ULTRAPORTABLE PLUS X-ray digital system is		

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
	predominantly employed in various settings, including health-care centres, temporary and emergency health centres (established, especially in pandemic circumstances), outreach and field interventions (such as mobile clinics/vans, screening campaigns, and home care), and tele-radiology solutions in remote areas. The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management.		
Multiple Use	Yes	Yes	Identical
Prescription (Rx only)	Yes	Yes	Identical
Anatomical Site	Body extremities	Body extremities	Identical
Intended User	The main users of the system are expected to be radiographers, radiological technologists and medical professionals trained on safety, radiation protection and image management.	Intended for use by a qualified/trained physician or technician	Identical
Use Environment	The PRORAD ATLAS X-Ray System is primarily used in:	Remex KA6 is intended for use in emergency room,	Identical

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
	Health-Care Centers; temporary and emergency Health-Centers (also established in Pandemic circumstances); outreach and field interventions (i.e.: mobile clinics/ vans, screening campaigns, home care); tele-radiology solutions in remote areas.	nursing home, NICU, operating room, ICU, negative pressure isolation room (NPIR)	
Size: Body	220 x 170 x 135mm (LxWxH)	165 x 176 x 255 mm	Different The subject device has been verified and validated. Therefore, the difference in size does not raise any concerns regarding the safety or performance of the device.
Weight	2.8 kg (Including Battery)	2.4 kg (including cone 190g)	Different The subject device has been verified and validated. Therefore, the difference in weight does not raise any concerns regarding the safety or performance of the device.
Energy Source	PRORAD ATLAS ULTRAPORTABLE: Lithium-Ion Polymer Rechargeable Batteries (11.1VDC), 100 exposures per charge	Lithium Polymer Rechargeable Battery (22.2 VDC), 300 exposures per charge	Different Due to the difference in battery capacity between the subject and predicate devices,

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
	PRORAD ATLAS ULTRAPORTABLE PLUS: Lithium-Ion Polymer Rechargeable Batteries (22.2VDC), 100 exposures per charge		there is a variation in the number of exposures. However, this does not impact the safety or performance of the device.
Mounting method	Unit is usually mounted on tripod/stand	Unit is usually handheld, or mounted on optional arms or tripod	Identical
User Interface	Up-Down pushbuttons for selection of exposure time, increase and decrease with LED indicators, laser ON/OFF	Up-Down pushbuttons for selection of exposure time, kVp, and mA, with LED indicators	Different The differences in the user interface do not raise any new concerns of safety or performance and this has been demonstrated through relevant validation.
Exposure switch	Dual-Stage, Exposure Hand switch	Dual-stage, Deadman type	Identical
Software	PRORAD ATLAS ULTRAPORTABLE Software	Built-in Software - S/W name: RPG-F-0706 - S/W version: 1.00	Different The PRORAD ATLAS X-Ray System uses its own software, which has been verified and validated. Therefore, this does not raise any concerns regarding the safety and performance of the device.
Exposure times	PRORAD ATLAS ULTRAPORTABLE: 0.01-0.1 sec (0.01 sec steps) 0.1-0.5 sec(0.02 sec steps) 0.5-1.0 sec(0.05 sec steps) 1.00-1.30 sec(0.1 sec steps)	0.06 -2.0 sec (0.01 sec. steps)	Different The difference in the exposure does not change the intended application. As per the standard of care and

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
	PRORAD ATLAS ULTRAPORTABLE PLUS: 0.05-0.10 sec(0.01 sec steps) 0.10-0.50 sec(0.02 sec steps) 0.50-1.00 sec(0.05 sec steps) 1.00-1.30 sec(0.1 sec steps) 1.30-2.00 sec(0.2 sec steps)		guidelines, the user can set the appropriate exposure time required for the examination. Therefore, this does not raise any concerns regarding the safety and performance of the device.
Tube potential (kV)	70 kVp	40 - 70 kVp (1 kVp steps)	Similar
Tube current (mA)	PRORAD ATLAS ULTRAPORTABLE: 2 mA PRORAD ATLAS ULTRAPORTABLE PLUS: 6 mA	2 mA - 6 mA (1 mA steps)	Similar
Alerts and Alarms	At least two specific alerts and alarms indicate equipment state of readiness to use	At least three specific alerts and alarms indicate equipment state of readiness to use.	Different The devices are designed to ensure safe operation for the operator and the patient. Verification and validation activities have been carried out to demonstrate that the subject performs as intended and is safe.
X-ray Tube	PRORAD ATLAS ULTRAPORTABLE: RADII KL11-0.4-70 Series PRORAD ATLAS ULTRAPORTABLE PLUS: OX-80	Canon D-041SB	Different The subject device utilizes a different x-ray tube when compared to the predicate device. The device has been tested, and it has been demonstrated that the device performs as intended and is safe. Therefore, this does not

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
			raise any concerns regarding the safety and performance of the device
Focal spot size	PRORAD ATLAS ULTRAPORTABLE: 0.4 mm PRORAD ATLAS ULTRAPORTABLE PLUS: 0.8 mm	0.4 mm	Different The focal spot size of the PRORAD ATLAS ULTRAPORTABLE is identical to that of the predicate device, and the focal spot size of the PRORAD ATLAS ULTRAPORTABLE PLUS falls outside of the predicate device. The device has been tested, and it has been demonstrated that the device performs as intended and is safe. Therefore, this does not raise any concern regarding the safety and performance of the device.
Total filtration	1.5 mm AL Eq	1.6 mm Al equivalent	Different The subject device has been validated and tested to demonstrate that the difference in total filtration does not raise any new questions of safety or performance of the device.
Image receptor	Digital radiography	Digital radiography	Identical
Collimator	Beam limiting device with crosshair laser light	Square collimator with LED Light Field Center Indicator	Different

Comparable Properties	Subject Device	Predicate Device (K212144)	Comparison Results
			The principle of operation and usage of the collimator in the subject device and predicate device remains the same. The subject device has been validated and tested to demonstrate that the different collimator does not raise any new questions of safety or performance of the device.
Triggering mechanism	Two stage triggering	Two stage triggering	Identical
Performance standard	IEC 60601-1-3:2008+AMD1:2013 +AMD2:2021 IEC 60601-2-54:2022	IEC 60601-1-3:2013 IEC 60601-2-28:2017 IEC 60601-2-54:2009	Identical
Electrical safety	IEC 60601-1:2005 12+AMD1:2012-07+AMD2:20 2008 IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-3:2008+AMD1:2013 +AMD2:2021 IEC 60601-2-54:2022 IEC 62304:2015 IEC 62366-1:2020	IEC 60601-1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2013 IEC 62304:2006 IEC 62366:2007	Identical

Discussion of similarities and differences

PRORAD ATLAS X-Ray System is intended for X-ray imaging of human anatomy in adult and paediatric populations. The primary users anticipated for the system include radiographers, radiological technologists, and medical professionals who are trained in safety, radiation protection, and image management. The subject device and predicate device are intended for use on body extremities. The subject device utilizes FDA-cleared X-ray flat panel detectors. The other components of the imaging system, such as the X-Ray generator and X-Ray tube, are either identical or similar to the predicate device. Both the subject and predicate device are powered by a rechargeable battery and operated by push buttons and/or a touch screen on the device itself. There are minor differences in the technical specifications of the subject and predicate devices; however, these differences do not raise any new issues of safety or performance.

Summary of non-clinical testing

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

1. IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-2:2014+AMD1:2020 CSV Consolidated Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
3. 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
4. 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
5. IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices.
6. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes.
7. ISO 14971:2019 Medical devices — Application of risk management to medical devices.
8. ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
9. ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices — Information to be supplied by the manufacturer.

10. ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
11. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions | FDA (Document issued on June 27, 2025).
12. Content of Premarket Submissions for Device Software Functions | FDA (Document issued on June 14, 2023).

The devices have been developed as per 21 CFR 820 and have completed design control activities, including risk management, verification, and validation.

Validation of PRORAD ATLAS X-Ray System has demonstrated that the system enables optimal and quality imaging of anatomical structures.

Summary of clinical testing

Clinical images of body extremities were collected from patients of varying ages, weights, and BMIs. These images were reviewed by a qualified radiologist, who confirmed that the images obtained using the PRORAD ATLAS ULTRAPORTABLE and PRORAD ATLAS ULTRAPORTABLE PLUS are clinically acceptable.

Conclusion

All the above details collectively demonstrate that PRORAD ATLAS X-Ray System is safe and effective when the device is used as labelled and is substantially equivalent to the predicate device.