May 19, 2025

Nanjing Perlove Medical Equipment Co., Ltd.
% Jack Fang
Official Correspondent
APlus Healthcare Technology (Shanghai) Co., Ltd.
Room 223, Building 17, JY-WISDOMBAY, Huqing Road 158,
Baoshan District
SHANGHAI, 200431
CHINA

Re: K243411
Trade/Device Name: Diagnostic X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: November 1, 2024
Received: April 18, 2025

Dear Jack Fang:

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)*
K243411

Device Name
Diagnostic X-ray System

Indications for Use *(Describe)*
The Diagnostic X-ray System is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

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

I Submitter

Nanjing Perlove Medical Equipment Co., Ltd.

No. 97 and No. 99 Wangxi Road, Jiangning District, Nanjing, 211100 Jiangsu, P.R. China

Contact person:

Official Correspondent: Jack Fang
APlus Healthcare Technology (Shanghai) Co., Ltd.
Add: Room 223, Building 17, JY-WISDOMBAY, Huqing Road 158, Baoshan District, Shanghai, 200431 China
Tel: +8613161499974
E-mail: jack.fang@ap-healthcare.com

Preparation date: May 17th, 2025

II Proposed Device

Trade Name of Device:	Diagnostic X-ray System
Models:	PLX119C
Regulation name:	Image-intensified fluoroscopic x-ray system
Regulation Number:	21 CFR 892.1650
Regulatory Class:	Class II
Product code:	OWB
Review Panel:	Radiology

III Predicate Device

510(k) Number: K222080
Product Code: OWB
Classification: 21 CFR 892.1650
Trade Name: Garion
Regulatory Class: II

IV Device description

The Diagnostic X-ray System is a mobile (within an imaging facility) general-purpose diagnostic fluoroscopic X-ray system that uses a C-arm and digital techniques for image capture, display and manipulation and is designed to be used in a variety of general-purpose applications requiring real-time fluoroscopic imaging capabilities.

The Diagnostic X-ray System is consists of X-ray source assembly (combined type), collimator, flat-panel detector, image processing workstation, C-arm and mobile rack, Medical Image Workstation Software.

Principles of Operation

Based on the principle that different tissues and organs of the human body have different attenuation of X-ray, the X-ray tube (an evacuated tube with an anode and a

cathode) emits X-rays that passing through the patient's body. The detector converts the X-rays into visible images that are displayed on the C-arm monitor. The C-shaped connecting element allows movement horizontally, vertically and around the swivel axes, so that X-ray images of the patient can be produced from almost any angle.

V Indications for use

The Diagnostic X-ray System is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

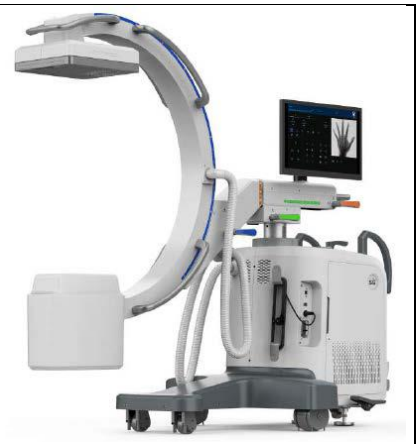
VI Comparison of technological characteristics with the predicate device

The comparison between the overall specifications of the predicate device and the proposed device is shown in Table 1. Comparison between the Diagnostic X-ray System and the predicate device was conducted with respect to intended use, technological characteristics and principles of operations, providing more detailed information regarding the bases for the determination of substantial equivalence.

Table 1 Comparison of technological characteristics with the predicate device

Items	**Proposed Device** Diagnostic X-ray System	**Predicate Device** **Garion** K222080
Indications for use	The Diagnostic X-ray System is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.	The Garion is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

X-ray Tube	Anode Type	Fixed Anode		Rotating Anode
	Anode target angle	15°		10°
	Focal size	0.6/1.8		0.3/0.6
Fluoroscopic Mode	kV range	40-120 kV		40-125 kV
	mA range	0.3-100 mA		0.1-100 mA
	Pulse Fluoro	YES		YES
	ABS function	YES		YES
Detector	Manufacture and Model	THALES Pixium3030S	IRAY's Mercu 0909F	IRAY's, Mercu 0909F
	Size	12" x 12"	9" x 9"	9" x 9"
	Scintillator	Cesium Iodide	Cesium Iodide	Cesium Iodide
	Detector type	amorphous silicon detector	amorphous silicon detector	amorphous silicon detector
	Active detector size	300 mm x300 mm	228.6 mm x228.6 mm	228.6 mm x228.6 mm
	Total pixel matrix	1956x1956	1024×1024	1024×1024
	Pixel pitch	154 μm	205 μm	205 μm
	A/D Conversion	16 bit	16 bit	16 bit
	MTF @ 1.0 LP/mm	Typical 59%	Typical 64%	Typical 64%
	DQE @ 0 LP/min	Typical 77%	Typical 77%	Typical 77%
C arm	SID	1000mm		980mm
	Range of C-arm Rail Rotation	±180°		±180°
	Range of the Linear FR-arm Movement	200mm		200mm
	Range of the Liner T-arm Movement	400m		400m
	Range of swing-arm Rotation	±15°		±15°
Collimator		Motor control / rotation		Motor control / rotation

Photo		

VII Performance Data

The following performance data were provided in support of the substantial equivalence determination. Electrical safety and electromagnetic compatibility (EMC) testing were conducted on the proposed device. The system complies with IEC 60601-1-2: 2014+AMD1:2020 / EN 60601-1-2: 2015+A1: 2021, IEC 60601-2-54: 2009+AMD2:2018 / EN 60601-2-54: 2009+A2:2019, IEC 60601-1-3:2008 +A1:2013+A2:2021/EN 60601-1-3:2008+A1:2013+A2:2021 and IEC 60601-2-43:2010+A1:2017+A2:2019/ EN 60601-2-43:2010+A1:2018+A2:2020.

Non-Clinical Testing

Bench testing of the detector imaging metrics was carried out and performance characteristics were measured and compared with the predicate.

Clinical images of multiple body parts were taken using radiography and fluoroscopy, with motion, to demonstrate acceptable imaging performance of the Diagnostic X-ray System. The clinical images were reviewed and assessed by a qualified radiologist.

Software

- Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Software Contained in Medical Devices." The Embedded software and the workstation software for this device required basic level documentation, since a failure a failure or flaw of device software function(s) would not present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

- Cybersecurity

The cybersecurity documentation was provided according to FDA guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Usability

Usability validation was performed and documentation was provided complies with IEC 60601-1-6 and IEC 62366-1.

Biocompatibility

The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1:2018 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

VIII Clinical Testing

No clinical study is included in this submission.

IX Conclusion

The proposed device has the same indications for use and has similar design features and technological characteristic as the predicate device. The differences between the predicate device and the proposed device do not raise new questions of safety or effectiveness. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.