August 25, 2021

Nanjing Perlove Medical Equipment Co., Ltd.
% Stuart Situ
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza,
West Guangzhong Road 555
Shanghai, 200071
CHINA

Re: K212134
Trade/Device Name: Diagnostic X-ray System/PLX5200A
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: June 15, 2021
Received: July 8, 2021

Dear Stuart Situ:

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,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.08.25 09:52:14 -04'00'

, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212134

Device Name
Diagnostic X-ray System
PLX5200A

Indications for Use *(Describe)*
The PLX5200A is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions.
It is not intended for mammography.

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

K212134

I Submitter

Nanjing Perlove Medical Equipment Co., Ltd.
No.97&99, Wangxi Road, Jiangning District, Nanjing 211100, Jiangsu, China

Contact person:

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E-mail: ce@perlove.com.cn
Preparation date: Aug 10, 2021

II Proposed Device

Trade Name of Device:	Diagnostic X-ray System PLX5200A
Models：	PLX5200A
Regulation name:	Mobile X-Ray System
Regulation Number:	21 CFR 892.1720
Regulatory Class:	Class II
Product code:	IZL, MQB,
Review Panel	Radiology

III Predicate Devices

a. 510(k) Number: K192011
Product Code: IZL, MQB
Classification: 21 CFR 892.1720
Trade/Device Name: PhoeniX
Manufacturer: SEDECAL SA
Regulation Name: Mobile x-ray system
Regulatory Class: Class II

b. 510(k) Number: K201340
Product Code: IZL, MQB
Classification: 21 CFR 892.1720
Trade/Device Name: AQUILA 320 D / AQUILA 320 S
Manufacturer: VMI Tecnologias LTDA

Regulation Name: Mobile x-ray system
Regulatory Class: Class II

IV Reference Devices

a. 510(k) Number: K150929
Product Code: MQB
Regulation Name: Stationary x-ray system
Regulatory Class: II
Classification: 21 CFR 892.1680
Trade/Device Name: CareView 1500Cw X-Ray Flat Panel Detectors
Manufacturer: CARERAY DIGITAL MEDICAL SYSTEM CO., LTD.

b. 510(k) Number: K201004
Product Code: MQB
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Classification: 21 CFR 892.1680
Trade Name: Wireless Digital Flat Panel Detector
Model Name Mars1417V-TSI
Manufacturer: IRay Technology Taicang Ltd.

V Device description

The proposed device is a mobile x-ray system, it uses digital techniques for image capture, display and manipulation and the mobile design allows it to operate on mains or battery power and to be driven or pushed by an operator to various locations within a building or facility. It is commonly used for bedside imaging. This system consists of a mobile base unit, combined X-ray tube assembly, collimator, frame, X-ray flat panel detector, and image processing system, see figure V.1

Figure V.1 Picture Illustration of PLX5200A

Principles of Operation

X-rays are produced by the x-ray tube (an evacuated tube with an anode and a cathode) when a stream of electrons, accelerated to high velocities by a high-voltage, collides with the tube's target anode. Collimator confines the primary beam to the approximate size and shape that will cover only the area of diagnostic interest. The device is equipped with wireless x-ray flat panel detectors, which use a scintillator material to convert x-rays to visible light. An array of photodiodes on the scintillator layer absorbs the light and translates it into a signal for digital display.

PLX5200A is used for moving to a ward, an operation room, etc., and photographing the patient who is not suitable for moving.

PLX5200Ais configured with a 150kHu x-ray tube, a manual collimator, and small, light, wireless, easy handling portable DR detectors: CareView 1500Cw, and Mars1417V-TSI (both are FDA cleared) with capacity of wireless image capture and transmission technology. The wheeled image process system integrates the touch screen image acquisition computer with workstation software installed, and 50kw high frequency generator with micro-processor controls.

Software

The software of the Mobile Digital Radiography System includes an embedded software and a workstation software. The embedded software in the diagnostic system intended to control X-rays generation for examination of various anatomical regions. The workstation software is installed in the computer or tablet to complete the image data acquisition, image display, image processing, film printing, reporting, image transmission and other clinical work, such as registering patients' information, acquiring images, viewing images, writing and printing diagnostic report, DICOM file sending, DICOM film printing, database backup and restore, etc, which provide an effective means to manage medical image information for hospitals.

The level concern of the software of this device is Moderate.

VI Indication for use

The PLX5200A Mobile X-ray system is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions.

It is not intended for mammography.

VII Comparison of technological characteristics with the predicate devices

The comparison between the overall specifications of the predicate devices and the proposed device (PLX5200A) is shown in Table 1. Any differences between the predicate and subject devices have no impact on safety or effectiveness of the subject devices and do not raise any potential safety risks.

Item	Proposed device	Predicate device 1 (K192011)	Predicate device 2 (K201340)	Discussion
Model name	PLX5200A	PhoeniX	AQUILA 320 D / AQUILA 320 S	-
Product Code	IZL, MQB,	IZL, MQB	IZL, MQB	same
Regulation No.	21 CFR 892.1720	21 CFR 892.1720	21 CFR 892.1720	same
Class	Class II	Class II	Class II	same
Indication for use	The PLX 5200A Mobile X-ray system is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. It is not intended for mammography.	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography	same
X-ray generator rating	50 kW	20 kW, 32 kW, 40 kW and 50 kW.	35.2 kW only	

				Same with PhoeniX's max rating.
X-ray voltage range	40-150kV in 1 kV steps	From 40 kV to 150 kV in 1 kV steps	From 40 to 125 kV in 1 kV steps	same with PhoeniX.
mARange	10~500mA	From 10 mA to 630 mA / 640 mA /650 mA.	From 20 to 320 mA	similar
X-ray Tube	0.6/1.2, 150kv max;	E7886 0.7/1.3, 150kv max. XRR-3331: 0.6/1.2, 150kv max	Unknown	Similar The same with one of PhoeniX's tube.
Collimator	X5300: Manually, with added filtration 1.0mmAl/2.0mmAl; Inherent filtration: 1.5mmAl	Ralco R108F (Two versions, see details in PHOTOS item in K192011 summary.) Manually. Parameters are unknown	Choice of Models Leadmec Collimator – LDM206 Ralco Collimator – R104 Ralco Collimator – R104/A Ralco Collimator – R108 SM Collimator – 38A Parameters are unknown All collimators meet the US Performance Standard	Different

Collimator operation method	Manually adjustable collimator	Manually	Unknown	Same with PhoeniX.
Pixel pitch	CareView 1500Cw: 154 μm Mars1417V-TSI: 150 μm	125um	Pixel pitches from 120 to 154μm	similar
Effective reception field	14 in. x 17 in;	17 in. x 17 in; 14 in. x 17 in; Or 11in×14in;	43x43cm, 35x43cm or 24x30cm	Same with PhoeniX's one option.
Spatial resolution	Min 3.3lp/mm;	unknown	Min 3.3lp/mm;	Same with AQUILA 320 D / AQUILA 320 S
Software	PLX5200 workstation software 5200 Embedded Software	Canon control software CXDI-NE	DROC Software for Careray Detectors, (K201058 and others) ECONSOLE Software for DRTECH Detectors. K152172	Different
Power Source	230V~, 50/60Hz 110V~, 60Hz And battery.	Universal power supply, from 100 V~ to 240 V~. 1 phase, 1.1 kVA	110/115/127/220/230 VCA-50/60 Hz and Batteries	similar
Meets US Performance Standard	YES 21 CFR 1020.30 and 1020.31	YES 21 CFR 1020.30	YES 21 CFR 1020.30 and 1020.31	same
Panel Interface	Ethernet or Wi-Fi wireless	Ethernet or Wi-Fi wireless	Ethernet or Wi-Fi wireless	same

The differences between the proposed device and the predicate device are the collimator and the software. The proposed device collimator (X5300) was tested with the system according to FDA

recognized standards ANSI/AAMI ES60601-1, IEC60601-1-3 and IEC 60601-2-54. The proposed software: PLX5200 workstation software and 5200 Embedded Software were validated and comply with FDA recognized standard IEC 62304.

The results of non-clinical bench performance testing indicate that the proposed deviceare as safe and effective as the predicate devices.

VIII Performance Data

The following performance data were provided in support of the substantial equivalence determination.
Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the proposed device. The system complies with IEC 60601-1:2005+A1:2012 / ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, IEC 60601-1-3:2008+A1:2013, IEC 60601-2-54:2009 , IEC 62471 standard for safety, and and IEC 60601-1-2: 2014 standard for EMC， and Radio frequency (RF) wireless coexistence of equipment testing was performed according to IEEE ANSI C63.27-2017 American National Standard for Evaluation of Wireless Coexistence.

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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The Embedded software and the workstation software for this device was considered as a "Moderate" level of concern, since a failure could result in minor injury to the patient or operator.

· Cybersecurity

The cybersecurity documentation was provided according to Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

· DICOM

DICOM declaration was provided according to FDA recognized standard NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set.

Usability Testing

Usability validation was performed and documentation was provided complies with FDA recognized standard IEC 60601-1-6 Edition 3.1 and EC 62366-1 Edition 1.0.

Risk management

Risk management activities were performed throughout the device life time, and the documentations were provided according to FDA recognized standard ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices.

Biocompatibility Testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The biocompatibility testing for the x-ray flat panel detector includes the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin irritation
-

IX Clinical Testing

No clinical study is included in this submission.

X Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. 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.