May 4, 2022

Yian Medical Technology (Haining) Co., Ltd
Zhiqin Yu
RA Supervisor
1st Floor Area 1, 2nd Floor Area 1, Building A,
No. 2 Caohejing Road, Haining Economic Development Zone
Jiaxing, Zhejiang
CHINA

Re: K220700
Trade/Device Name: Heart5R-110 Portable X-Ray Machine, Heart3R-110 Portable X-ray Machine
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: February 28, 2022
Received: March 10, 2022

Dear Zhiqin Yu:

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 Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT 8B: Division of Radiological Imaging and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement (FDA form 3881)

Heart5R-110, Heart3R-110

Portable X-ray Machine

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)*
K220700

Device Name
Heart5R-110 Portable X-ray Machine
Heart3R-110 Portable X-ray Machine

Indications for Use *(Describe)*

The Heart5R-110, Heart3R-110 are Portable X-ray Machine, intended for use by a qualified/trained physician or technician on adult population for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).

The system is subject to the following limitations of use when stand-mounted:
- The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities.
-The device may be used for imaging of the chest when used without a grid.

This device 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.

Section 5: 510(k) Summary

Heart5R-110, Heart3R-110

Portable X-ray Machine

510(k) Summary
(K220700)

Date Prepared:	Feb 28, 2022
Manufacturer:	Yian Medical Technology (Haining) Co., Ltd 1st Floor Area 1, 2nd Floor Area 1, Building A, No. 2 Caohejing Road, Haining Economic Development Zone, Haichang Street, Haining City, Jiaxing City, Zhejiang Province, China
Contact Person:	Zhiqin Yu RA Supervisor Yian Medical Technology (Haining) Co., Ltd Tel: +86-0573-87217250 zhiqin.yu@yian-medical.com

Identification of the Device:

Proprietary/Trade Name:	Heart 5R-110 Portable X-Ray Machine Heart 3R-110 Portable X-Ray Machine
Classification Name:	Mobile x-ray system
Regulatory Number:	21 CFR Part 892.1720
Product Code:	IZL
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	SR-8230 Portable X-ray Unit SR-8230S Portable X-ray Unit
Classification Name:	Mobile x-ray system
Regulatory Number:	21 CFR Part 892.1720
Product Code:	IZL
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI).
Clearance:	K200976 (cleared June 10, 2020)

Device Description:

The Portable X-ray machine directly provides rays for diagnostic operation, which is composed of the following parts: power supply circuit, inverter, high-voltage tank ball tube, filament circuit, control circuit, high-voltage cabinet body, user interface and collimator.

The differences between the Heart 5R and Heart 3R models:

Model	Heart 5R-110	Heart 3R-110
Power	5KW	3KW
KV range	40 to 125 kV	
KV precision	≤±8%	
mA range	10mA to 100mA	10mA to 71mA
mA precision	≤±20%	
ms range	1~2000ms	
ms precision	≤±(10%+1ms)	
mAs range	0.1mAs to 100mAs	
mAs precision	≤±(10%+0.2mAs)	
Nominal focus size	0.6/1.8	
The anode target Angle	15°	
Tube core inherently filtered	0.65mmAL/75KV	

The software is Moderate level of concern, it is original software, and it is not a software for image analysis.

Any x-ray detectors (necessary for a fully-functional x-ray system) are not part of the current submission.

Indications for Use:

The Heart5R-110, Heart3R-110 are Portable X-ray Machine, intended for use by a qualified/trained physician or technician on adult population for the purpose of acquiring X-ray images of the desired parts of patient’s anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).

The system is subject to the following limitations of use when stand-mounted:

- The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities.

-The device may be used for imaging of the chest when used without a grid.

This device is not intended for mammography.

Standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-3 Edition 2.1 2013-04 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 Edition 3.1 2013-10Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-28 Edition 3.0 2017-06 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- ISTA 3B 2017 Packaged-Products for Less-Than-Truckload (LTL) Shipment
- IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- ISO 20417:2021 Medical devices-Information to be supplied by the manufacturer
- FCC Part 15 Radio Frequency Devices of Part 15B and Part 15C

FDA Guidance Documents:

- “Format for Traditional and Abbreviated 510(k)s Guidance” issued on September 13, 2019.

- Radio Frequency Wireless Technology in Medical Devices
- Guidance for Medical X-ray Imaging Devices Conformance with IEC Standards

Performance standard:

- 21CFR PART 1010 PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL
- 21 CFR 1020.30: Diagnostic x-ray system and their major components
- 21 CFR 1020.31: Radiographic Equipment

Comparison with Predicate Device:

The Heart5R-110, Heart3R-110 Portable X-ray Machine and its predicate device, have the equivalent intended use, functions and similar physical characteristics, performance characteristics.

Substantial Equivalence:

The comparison between the overall specifications of predicate device (SR-8230/SR-8230S) and the new device (Heart5R-110, Heart3R-110) is shown in Table 1, and the comparison between the Collimator specifications of reference device (SR-8230/SR-8230S) and the new device (Heart5R-110, Heart3R-110) is shown in Table 2. Any differences between the predicate and the new device have no impact on safety or efficacy of the new device and do not raise any new potential or increased safety risks, and the new device is equivalent in performance to existing legally marketed devices.:

Description	Subject Device Heart5R-110, Heart3R-110	Predicate Device SR-8230/SR-8230S (K200976)
Indications for use	The Heart5R-110, Heart3R-110 are Portable X-ray Machine, intended for use by a qualified/trained physician or technician on **adult** population for the purpose of acquiring X-ray images of the desired parts of patient’s anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). The system is subject to the following limitations of use when stand-mounted: - The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities. -The device may be used for imaging of the chest when used without a grid.	The SR-8230/SR-8230S Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient’s anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). The device may be used for handheld diagnostic imaging of body extremities. The system is subject to the following limitations of use when stand-mounted: - The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities. -The device may be used for imaging of the chest when used without a grid. This device is not intended

Description	Subject Device Heart5R-110, Heart3R-110	Predicate Device SR-8230/SR-8230S (K200976)
	This device is not intended for mammography.	for mammography.
Weight	17.6kg(Including Collimator)	15kgs(33.06lb) (Including Collimator)
Size	367mm×251mm×228mm	460mm×245mm×188mm
Use Interface	Soft touch push buttons	SR-8230: Soft touch push buttons SR-8230S: Touch screen
Exposure time	0.001sec~2sec : R'20 sec Step	0.02 sec – 6.3 sec: R'10 sec Step
Memory Settings (technique)	14 memories	16 memories
HF Generator	High Frequency	High Frequency
kW	5.0KW(Heart5R-110) 3.0KW(Heart3R-110)	5.0kW
kVp	40-125kVp	40-125kVp
mA	10mA-100mA (Heart5R-110), 10mA-71mA (Heart3R-110): R'20 sec Step	10mA-100mA: R'10 sec Step
FDA Performance Standard	Complies	Complies
Collimator	CRUX707i	SIUI SR-8200-39L
Output Rating	Max. 5.0kW(50mA@100kV)	Max. 5.0kW(40mA@125kV)
Type	Microprocessor controlled High Frequency inverter	Microprocessor controlled High Frequency inverter
kV Range	40~125kV,86 Step (1kV Step)	40~125kV,86 Step (1kV Step)
mA Range	10~100mA,21 Steps (10,11,12.5,14,16,18,20,22,25,28,32,36,40,45,50,56,63,71,80,90,100mA)	10~100mA,11 Steps (10,12.5,16,20,25,32,40,50,64,80,100mA)
Exposure	0.001sec~2sec : R'20 sec Step	0.02~6.3seconds,

Description	Subject Device Heart5R-110, Heart3R-110	Predicate Device SR-8230/SR-8230S (K200976)
Time		26 Step (in 25% Steps)
mAs Range	0.1~100mAs, 50 Step	0.4~200mAs, 28 Step (in 25% Steps)
X-ray Tube Type	Stationary Anode	Stationary Anode
Focal Spot Size (Small/Large)	0.6/1.8mm	0.6/1.8mm
Anode Heat Storage Capacity	42,000HU	42,000HU (30,000J)
Power Cord Length	2.08m	3m
Exposure Hand-switch Cord Length	5m	6m (Max. Length)
X-ray switching frequency	60KHZ	100kHz
Control	2 Point Control (kV, mAs)	2 Point Control (kV, mAs)
Anatomical Programs	Preprogrammed 16 APR data-User Programmable	Preprogrammed 16 APR data-User Programmable

Table 2 Collimator Specs Comparison

Description	Subject Device Heart5R-110，Heart3R-110	Predicate Device SR-8230/SR-8230S (K200976)
Model	CRUX707i	SR-8200-39L
Manufacturer	Yian	SIUI
Control	Manual control	Manual with 15, 30, 45, 60sec. Lamp timer

Field Shape	Rectangular	Rectangular
Max. Field Size	43x43cm (at 100cm SID)	44x44cm (at 100cm SID)
Leakage Radiation	< 1mGyh. (at SID 1m)	< 40mR/hr. (at SID 1m)
Max. kVp shield	150kV	150kV
Inherent Filtration	1.0mmAl eq.	1.2mmAl eq.
Light source	9W LED	9W LED
Standard	Rotating flange	Rotating flange
Option	Ultrasonic distance measurement（Max.180cm)	Tape measure (Max.200cm)
Electrical Rating	24V AC/DC, Max.4A	3-12VDC,10W
Dimension/ weight	139.3(W) × 166.5(D) × 83(H)mm / 1.5kg	170(W)×180(D)×105(H) mm / 1.2kg(2.65lb)

The subjected device and the predicted device are identical in the indications for use, patient population, use environment, and electrical safety. They are similar in technical specification. The differences between the proposed device and the predicate device will not raise any new issues of safety or effectiveness.

Summary of Testing:

Summary of Non-Clinical Tests:
Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:
•ANSI/AAMI ES:60601-1:2005/A2:2010
•IEC 60601-1-3 Edition 2.1 2013-04
•IEC 60601-2-28:2017, Part 2-28
IEC 60601-2-54:2018, Part 2-54
•IEC 60601-1-2:2014
Bench Testing Summary
The verification test results showed compliance with the above standards. Validation was performed for overall operation by taking and reviewing test

images. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the primary predicate.

Summary of Clinical Tests:
The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:
The conclusions drawn from the nonclinical tests demonstrate that the subject device, Heart5R-110, Heart3R-110 Portable X-ray Machine is substantially equivalent to the predicate devices.