December 23, 2020

Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
℅ Flower Cai
Liaison Manager
77 Jinsha Road
Shantou, Guangdong 515041
CHINA

Re: K202353
Trade/Device Name: SR-2300 Portable DR Imaging System, SR-2300S Portable DR Imaging System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL, MQB, LLZ
Dated: November 20, 2020
Received: November 30, 2020

Dear Flower Cai:

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,

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)*
K202353

Device Name
SR-2300 Portable DR Imaging System
SR-2300S Portable DR Imaging System

Indications for Use *(Describe)*
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).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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is provided in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

The assigned 510(k) number is: K202353

5.1 Submitter

Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)

77 Jinsha Road, Shantou, Guangdong 515041, China

Tel: 86-754-88250150

Fax: 86-754-88251499

Contact Person: Flower Cai

Shantou Institute of Ultrasonic Instruments Co., Ltd.

77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: Nov 13, 2020

5.2 Device

Name of Device: SR-2300 Portable DR Imaging System

SR-2300S Portable DR Imaging System

Classification Name: Mobile x-ray system (21 CFR 892.1720)

Regulatory Class: II

Product Code: IZL, MQB, LLZ

5.3 Predicate Device

The SR-2300/SR-2300S Portable DR Imaging System is for X-ray imaging and diagnosis, image acquisition in facilities with mobile or fixing sites, and is substantially equivalent to the predicate device.

Name of Predicate Device: AcuityPDR (K200726)

Classification Name: Mobile x-ray system (21 CFR 892.1720)

Regulatory Class: II

Product Code: IZL, MQB, LLZ

5.4 Device Description

This SR-2300/SR-2300S Portable DR Imaging System is a portable digital device developed, designed and manufactured by SIUI. A detailed comparison table with an equivalent device is provided below. The device consists of the following major components: a portable X-ray unit, a flat panel detector, and workstation. The difference between SR-2300 and SR-2300S is the operation interface of the portable X-ray Unit only, while the flat panel detector and the workstation are the same for SR-2300 and SR-2300S. The SR-2300S has the display interface with button-operation digital tube, while the SR-2300 has the display interface with touch screen operation. Except for the difference above, the 2 models (SR-2300 and SR-2300S) are completely the same in all the other mechanical and circuit design. See the photos below (Fig. 1 and Fig. 2).

Fig.1 SR-2300S Portable DR Imaging System

Fig.2 SR-2300 Portable DR Imaging System

The major components of the X-ray main unit include: handle, enclosure, control panel, system control (SYS) board, high-voltage tank, collimator (beam limiter), lithium-ion battery and system control software running on the SYS board.

The system control software is for real-time interaction and control with various circuit modules inside the Portable DR Imaging System. The software responds to user operations on the control panel. The user can adjust and control the kV and mAs parameters, and the software will display the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the system control board, and control the high-voltage tank to generate high-voltage to excite the X-ray tube inside to emit X-rays, control the switch of the collimator indicator, and monitor the working status of the device, the battery power status, and control the display of the status indicators.

The system is for X-ray imaging and diagnosis in facilities with mobile or fixing sites. Since the kV range of this device is 40~125kVp, which is not suitable for breast exams, the device is not intended for mammography.

The flat panel detector is the core of image acquisition of the system. The X-ray emitted through the human body is converted by the scintillator of flat panel detector to visible optical signals, which are then converted to digital signals by the amorphous

silicon of flat panel detector. The processed digital signals are sent to the image workstation for image reconstruction, display, storage and transmission via a Gigabit Ethernet cable. The image workstation is installed with a PIE-5 DR Workstation, which is the core of image acquisition and processing on the system.

5.5 Indications for Use

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).This device is not intended for mammography.

5.6 Comparison of Technological Characteristics with the Predicate Device

The comparison between the overall specifications of the predicate device (AcuityPDR) and the new device (SR-2300/SR-2300S) is shown in Table 1. 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.

Table 1

Description	**Predicate Device AcuityPDR (K200726)**	**Subject Device SR-2300/SR-2300S**
Indications for use	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography.	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).This device is not intended for mammography.
X-ray Generator(s) Model	--	SR-8230 (K200976) or SR-8230S (K200976)
Generator Photos		SR-8230 SR-8230S  

Description		Predicate Device AcuityPDR (K200726)	Subject Device SR-2300/SR-2300S
Basic Generator Characteristics	**Peak generator**	2kW	5kW
	Tube current	40-60kV:25mA 61-100kV:20mA	10-100mA
	Tube voltage adjustable range	40-100kV,step value 1kV	40-125kV,step value 1kV
	mAs range	0.4mAs-50mAs,with the range of : 0.40,0.50,0.63,0.80,1.00,1.25,1.6,2.0,2.5,3.2,4.0,5.0,6.3,8,10,12.5,16,20,25,32,40,50	0.4mAs-200mAs,with the range of : 0.40,0.50,0.63,0.80,1.00,1.25,1.6,2.0,2.5,3.2,4.0,5.0,6.3,8,10,12.5,16,20,25,32,40,50,63,80,100,125,160,200
Collimator		Built in	Built in
X-ray Generator		One model ,up to 100kVp	One model ,up to 125kVp
Operator console		Touch Control or Touch Screen	Button Control or Touch Screen
Digital X-Ray Detectors		AcuityDR (K171137)	SFD-1X
Panel Shape		Rectangular Panel	Rectangular Panel
Detector Size		13” X 17”	14” X 17”
Pixel Pitch		140 μ m	150 μ m
Materials Scintillator		TFT –amorphous Silicon	TFT –amorphous Silicon
DQE		25% at 1.0 lp/mm 5% at 3.0 lp/mm	36% at 1.0 lp/mm 13% at 3.0 lp/mm
MTF		35% at 2.0 lp/mm	38% at 2.0 lp/mm
Communication Method		Wire Wireless IEEE 802.11a//g/n(2.4GHz/ 5GHz) Security: WEP/WPA/WPA2	Wire Wireless IEEE 802.11a//g/n(2.4GHz/ 5GHz) Security: WEP/WPA/WPA2
Acquisition Software		AccuVueMED (K152172)	PIE-5
Software function		Image viewing Image search Image storage Image annotation	Image viewing Image search Image storage Image annotation

Description	Predicate Device AcuityPDR (K200726)	Subject Device SR-2300/SR-2300S
	Image measurement Image processing Image stitch	Image measurement Image processing Image stitch
DICOM 3.0 Compatibility	Yes	Yes
Photos		 Note: The portable stand is an optional component.
Power Source	AC Line or rechargeable batteries (Generator only）	AC Line or rechargeable batteries

5.7 Non-clinical Testing Summary

The SR-2300/SR-2300S Portable DR Imaging System complies with and/or was tested in accordance with the following FDA guidance and International Standards:

- IEC 60601-1: 2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC60601-2-54:2009+A1:2015+A2:2018 Medical electrical equipment - Part 2-54:Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC60601-1-3: 2008+A1:2013 Medical electrical equipment Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment

- ISO 14971: 2007 Medical device - Application of risk management to medical devices
- ISO 10993-1: 2018 Biological evaluation of medical devices-Part1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization
- IEC 62304:2006+AMD1:2015 Medical device software – Software life cycle processes
- IEC 60601-1-6:2010+A1:2013 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – collateral standard: Usability
- IEC 62366-1:2015/COR1:2016 Medical devices – Application of usability engineering to medical devices
- ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ISO 13485 :2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Radio Frequency Wireless Technology in Medical Devices
- Guidance for the Pediatric Information for X-ray Imaging Device Premarket Notifications

The subject device and the predicate device are comparable in terms of technical features, general functions, applications and intended uses. The test results showed compliance with the above standards. Validation was performed for overall operation by taking and reviewing test images. Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the predicate device, but they provide further evidence in addition to bench testing data to show that the complete system works as intended. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the

predicate.

5.8 Software Description

The SR-2300/SR-2300S Portable DR Imaging System contains two software, one is the embedded software in the X-ray unit: system control software, and the other is PIE-5 DR Workstation (herein after referred to as “PIE-5”).

The system control software of SR-2300/SR-2300S is new software designed by SIUI. The software adopts development languages of keil, the program language is C language, the hardware platform is ARM. The system control software is for real-time interaction and control with various circuit modules inside the Portable DR Imaging System. The software responds to user operations on the control panel. The user can adjust and control the kV and mAs parameters, and the software will display the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the system control board, control the high-voltage tank to generate high-voltage to excite the X-ray tube inside to emit X-rays, control the switch of the collimator indicator, monitor the working status of the device and the battery power status, and control the display of the status indicators. The Level of Concern for the Software Device is Moderate.

The programming language of PIE-5 is C language, and the operating platform is Microsoft Windows. The software is a medical image processing system, consisting of image acquisition, image review and diagnosis, image processing and digital storage functions, which mainly address digital image workflow in radiographic department of hospitals. The functions of the software include patient registration, image acquisition and processing, image review and diagnosis, image printing, report editing and PACS transmission, digital image storage and recovery. The Level of Concern for the Software Device is Moderate.

5.9 Clinical Testing

Clinical testing is not necessary for the SR-2300/SR-2300S Portable DR Imaging System in order to demonstrate substantial equivalence to the predicate device.

5.10 Label

The labels on the device show that this device conforms to the following:

21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,

21 CFR 1020.30: Diagnostic x-ray systems and their major components,

21 CFR 1020.31: Radiographic Equipment .

5.11 Conclusion

The subject device SR-2300/SR-2300S system and the predicate device are comparable in terms of technical features, general functions, applications and indications for use.

Compared with the predicate device, the power of the SR-2300/SR-2300S is higher. The SR-2300/SR-2300S can be used for imaging including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities, and the predicate device AcuityPDR can be used for both adult and pediatric subjects for taking diagnostic x-rays. Nevertheless, it does not affect the safety and effectiveness of the SR-2300/SR-2300S, nor does it change the indications for use of the SR-2300/SR-2300S unit.

The indications for use of the SR-2300/SR-2300S Portable DR Imaging System do not create new potential safety risks, and its performance is comparable as that of the marketed products. Therefore, the device is as safe and effective as the legally marketed predicate device.