



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

January 6, 2021

Re: K202350

Trade/Device Name: SR-1000 Portable DR Imaging System, SR-1000S 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 23, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

## Indications for Use

510(k) Number (if known)  
K202350

Device Name

SR-1000 Portable DR Imaging System  
SR-1000S 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.

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## 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: K202350

### 5.1 Submitter

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

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Shantou Institute of Ultrasonic Instruments Co., Ltd.

77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: Aug 19, 2020

### 5.2 Device

Name of Device: SR-1000 Portable DR Imaging System

SR-1000S 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-1000/SR-1000S 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-1000/SR-1000S 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-1000 and SR-1000S is the operation interface of the portable X-ray Unit only, while the flat panel detector and the workstation are the same for SR-1000 and SR-1000S. The SR-1000S has the display interface with button-operation digital tube, while the SR-1000 has the display interface with touch screen operation. Except for the difference above, the 2 models (SR-1000 and SR-1000S) are completely the same in all the other mechanical and circuit design. See the photos below (Fig. 1 and Fig. 2).



Fig.1 SR-1000S Portable DR Imaging System



Fig.2 SR-1000 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-1000/SR-1000S) 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

<b>Description</b>	<b>Predicate Device AcuityPDR (K200726)</b>	<b>Subject Device SR-1000/SR-1000S</b>
<b>Indications for use</b>	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.
<b>X-ray Generator(s) Model</b>	--	SR-8100 (K200637) or SR-8100S
<b>Generator Photos</b>		<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>SR-8100</p>  </div> <div style="text-align: center;"> <p>SR-8100S</p>  </div> </div>

SIUI SR-1000/SR-1000S  
Portable DR Imaging System

Description		Predicate Device AcuityPDR (K200726)	Subject Device SR-1000/SR-1000S
<b>Basic Generator Characteristics</b>	<b>Peak generator</b>	2kW	2kW
	<b>Tube current</b>	40-60kV:25mA 61-100kV:20mA	40-60kV:25mA 61-100kV:20mA
	<b>Tube voltage adjustable range</b>	40-100kV, step value 1kV	40-100kV, step value 1kV
	<b>mAs range</b>	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-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
<b>Collimator</b>		Built in	Built in
<b>X-ray Generator</b>		One model, up to 100kVp	One model, up to 100kVp
<b>Operator console</b>		Touch Control or Touch Screen	Button Control or Touch Screen
<b>Digital X-Ray Detectors</b>		AcuityDR (K171137)	SFD-1X
<b>Panel Shape</b>		Rectangular Panel	Rectangular Panel
<b>Detector Size</b>		13" X 17"	14" X 17"
<b>Pixel Pitch</b>		140 μ m	150 μ m
<b>Materials Scintillator</b>		TFT –amorphous Silicon	TFT –amorphous Silicon
<b>DQE</b>		25% at 1.0 lp/mm 5% at 3.0 lp/mm	46.7% at 1.0 lp/mm 21.7% at 3.0 lp/mm
<b>MTF</b>		35% at 2.0 lp/mm	47.3% at 2.0 lp/mm
<b>Communication Method</b>		Wireless IEEE 802.11a//g/n(2.4GHz/5GHz) Security: WEP/WPA/WPA2	Wireless IEEE 802.11a//g/n(2.4GHz/5GHz) Security: WEP/WPA/WPA2
<b>Acquisition Software</b>		AccuVueMED (K152172)	PIE-5
<b>Software function</b>		Image viewing Image search Image storage	Image viewing Image search Image storage



<b>Description</b>	<b>Predicate Device AcuityPDR (K200726)</b>	<b>Subject Device SR-1000/SR-1000S</b>
	Image annotation Image measurement Image processing Image stitch	Image annotation Image measurement Image processing Image stitch
<b>DICOM 3.0 Compatibility</b>	Yes	Yes
<b>Photos</b>		 Note: The portable stand is an optional component.
<b>Power Source</b>	AC Line or rechargeable batteries (Generator only)	AC Line or rechargeable batteries

### 5.7 Non-clinical Testing Summary

The SR-1000/SR-1000S 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. 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-1000/SR-1000S 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-1000/SR-1000S 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-1000/SR-1000S Portable DR Imaging System in order to demonstrate substantial equivalence to the predicate device.

## **5.10 Conclusion**

The subject device SR-1000/SR-1000S 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-1000/SR-1000S is higher. The SR-1000/SR-1000S 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-1000/SR-1000S, nor does it change the indications for use of the SR-1000/SR-1000S unit.

The indications for use of the SR-1000/SR-1000S 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.