June 18, 2026

Shantou Institute of Ultrasonic Instruments Co., Ltd.
℅ Guang Chen
Primary Correspondent
#77, Jinsha Road
Shantou, CN 515041
CHINA

Re: K253058
Trade/Device Name: 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: May 20, 2026
Received: September 22, 2025

Dear Guang Chen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
DHT8B: Division of Radiologic 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)*
K253058

Device Name
Portable DR Imaging System

Indications for Use *(Describe)*
The Portable DR Imaging System 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 extremities.

This device is not intended for mammography.
This device is only intended for adults, not for paediatric application.
This device is only suitable for stand-mounted use in hospital shielded rooms.

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: K253058

1. Submitter

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

77 Jinsha Road, Shantou, Guangdong 515041, China

Tel: 86-754-88250151

Fax: 86-754-86603664

Contact Person: Chen Guang

Shantou Institute of Ultrasonic Instruments Co., Ltd.

77 Jinsha Road, Shantou, Guangdong 515041, China

Date Prepared: June 17, 2026

2. Subject Device

Name of Device: Portable DR Imaging System

510(k) submitter: SIUI

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

Regulatory Class: II

Product Code: IZL, MQB, LLZ

3. Predicate Device

Name of Device: SR-2300 Portable DR Imaging System (K202353)

510(k) holder: SIUI

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

Regulatory Class: II

Product Code: IZL, MQB, LLZ

Classification Name:

Mobile x-ray system	IZL	(per 21 CFR 892.1720)
Stationary x-ray system	MQB	(per 21 CFR 892.1680)
Medical image management and processing system	LLZ	(per 21 CFR 892.2050)

4. Device Description

The Portable DR Imaging System is a portable digital device developed, designed and manufactured by SIUI. The device consists of the following major components: a portable X-ray unit, a flat panel detector, and workstation.

This system is a Track 3 device. The Portable DR Imaging System contains two pieces of software, one is the embedded software in the X-ray unit: system control software, and the other is PIE-5 DR Workstation (hereinafter referred to as "PIE-5").

The system control software of the Portable DR Imaging System is software designed by SIUI. The software adopts development languages of Keil, the program language is C language, and 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 and 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.

PIE-5 uses the C programming 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.

5. Comparisons of SR-300Pro, SR-200Pro, SR-100Pro, SR-300, SR-200, SR-100, SR-2300Pro, SR-1100Pro, SR-1000Pro, SR-2300, SR-2000, SR-1100, and SR-1000 devices

The Portable DR Imaging System includes the models SR-300Pro /SR-2300 / SR-1000 / SR-2000 / SR-2300Pro / SR-1000Pro / SR-1100 /SR-1100Pro / SR-300 / SR-200 / SR-100 /SR-200Pro /SR-100Pro. These models used the same safe critical components, with the same circuit modules and working principles, and the same appearance. Except for the differences in functional configuration, these models are completely the same.

The mechanical structure is designed for market requirements of the devices according to international general safety standard (IEC 60601-1). The hardware design is identical to the following SR series models: SR-300Pro, SR-200Pro, SR-100Pro, SR-300, SR-200, SR-100, SR-2300Pro, SR-1100Pro, SR-1000Pro, SR-2300, SR-2000, SR-1100, and SR-1000. A list of the differences between various models intended for sale in the market is shown below, which are identical except for the differences in settings:

Table 1

Model	**DICOM Setting**	**Report Setting**	**Process Setting**	**Custom Setting**
SR-300Pro	Standard	Standard	Standard	Standard
SR-300	Standard	Standard	Standard	Optional
SR-200	Standard	Standard	Optional	Standard
SR-100	Standard	Optional	Standard	Standard
SR-200Pro	Optional	Standard	Standard	Standard
SR-100Pro	Standard	Standard	Optional	Optional
SR-2300	Standard	Optional	Standard	Optional
SR-1000	Standard	Optional	Optional	Standard
SR-2000	Optional	Standard	Standard	Optional
SR-2300Pro	Optional	Standard	Optional	Standard
SR-1000Pro	Optional	Optional	Standard	Standard
SR-1100	Standard	Optional	Optional	Optional
SR-1100Pro	Optional	Standard	Optional	Optional

6. Indications for Use

The Portable DR Imaging System 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 extremities.

This device is not intended for mammography.

This device is only intended for adults, not for pediatric application.

This device is only suitable for stand-mounted use in hospital shielded rooms.

7. Comparison of Technological Characteristics with the Predicate Device

The comparison between the overall specifications of the predicate device (K202353) and the subject device is shown in Table 2. Any differences between the predicate and the subject device have no impact on safety or efficacy of the subject device and do not raise any new potential or increased safety risks, and the subject device is equivalent in performance to existing legally marketed devices.

Subject Device：
Portable DR Imaging System (K253058)

Predicate Device: SIUI SR-2300 Portable DR Imaging System (K202353)

Description		**Subject Device： Portable DR Imaging System (K253058)**	**Predicate Device: SIUI SR-2300 Portable DR Imaging System (K202353)**
Indications for use		The Portable DR Imaging System 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 extremities. This device is not intended for mammography. This device is only intended for adults, not for pediatric application. This device is only suitable for stand-mounted use in hospital shielded rooms.	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.
Basic Genera-	**Peak generator**	150-560W	5kW

tor Charac-teristics	**Tube current**	1.6-8mA	10-100mA
	Tube voltage adjustable range	40-90kV, step value 1kV	40-125kV, step value 1kV
	mAs range	0.16mAs-8mAs	0.4mAs-200mAs
Collimator		Built in	Built in
X-ray Generator		One model	One model
Operator console		Touch Control or Touch Screen	Button Control or Touch Screen
Digital X-Ray Detectors		SFD-1X/ SFD-2X/ SFD-3X	SFD-1X
Panel Shape		Rectangular Panel	Rectangular Panel
Detector Size		Max: 14" X 17"	14" X 17"
Pixel Pitch		150μm	150μm
Materials Scintillator		TFT-amorphous Silicon	TFT-amorphous Silicon
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		PIE-5	PIE-5
Software Function		Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch	Image viewing Image search Image storage Image annotation Image measurement Image processing Image stitch
DICOM 3.0 Compatibility		Yes	Yes
Power Source		AC Line or rechargeable batteries (Generator only)	AC Line or rechargeable batteries

8. Non-clinical Testing Summary

The Portable DR Imaging System complies with and/or were tested in accordance with the following FDA guidance and International Standards:

- IEC 60601-1:2005+ AMD1:2012+AMD2:2020 Medical electrical equipment -

Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2021 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54:2022 Medical electrical equipment - Part 2-54:Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- ISO 14971:2019 Medical devices - 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 10993-10:2021 Biological evaluation of medical devices - Part 10:Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23:Tests for irritation
- IEC 62304:2006+A1:2015 Medical device software – Software life cycle processes
- IEC 60601-1-6:2010+ AMD1:2013+AMD2:2020 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366-1:2015+AMD1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - 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
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices

- Content of Premarket Submissions for Device Software Functions
- Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions
- Electromagnetic Compatibility (EMC) of Medical Devices

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.

Non-clinical Detector Performance testing as prescribed in the standard of IEC 60601-2-54: 2022.

9. Clinical Testing

SIUI performed Image Quality and Performance Testing by acquiring images of the extremities using both the Portable DR Imaging System (subject device) and the predicate device. The images were assessed for image quality and clinical utility by an ABR Board-Certified Radiologist. Comparative analysis demonstrated that the image quality of the subject device was substantially equivalent to that of the predicate device. The system exhibited sufficient clinical utility and fulfilled diagnostic requirements for extremities.

10. Conclusion

The subject device Portable DR Imaging System and the predicate device SIUI SR-2300 Portable DR Imaging System (K202353) are comparable in terms of technical features, general functions, applications and indications for use.