Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI) June 10, 2020
℅ Flower Cai
Liaison Manager
77 Jinsha Road
Shantou, Guangdong 515041
CHINA

Re: K200976
Trade/Device Name: SR-8230 Portable X-ray Unit
SR-8230S Portable X-ray Unit
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: April 10, 2020
Received: April 13, 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,

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)*
K200976

Device Name
SR-8230 Portable X-ray Unit
SR-8230S Portable X-ray Unit

Indications for Use *(Describe)*
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 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: K200976

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: June 4, 2020

5.2 Device

Name of Device: SR-8230 Portable X-ray Unit

SR-8230S Portable X-ray Unit

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

Regulatory Class: II

Product Code: IZL

5.3 Predicate Device

The SR-8230/SR-8230S Portable X-ray Unit 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: TR90BH

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

Regulatory Class: II

Product Code: IZL

Name of Reference Device: JADE Mobile X-Ray

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

Regulatory Class: II

Product Code: IZL

Legally Marketed Device	**Manufacturer**	**Model**	**510(k) Control Number**
Primary predicate device	MinXray, Inc	TR90BH	K182207
Reference device	DRGEM Corporation	JADE Mobile X-Ray	K183388

5.4 Device Description

This SR-8230/SR-8230S Portable X-ray Unit 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: an X-ray main unit, an exposure hand switch and a charger. The X-ray main unit is mainly for emitting X-rays required for X-ray exams; the hand switch is for output control of X-ray emitting, and the charger is for charging the built-in battery in the X-ray main unit. See the photos below (Fig. 1 and Fig. 2). The difference between SR-8230 and SR-8230S is the operation interface of the device only. The SR-8230 has the display interface with button-operation digital tube, while the SR-8230S has the display interface with touch screen operation. Except for the difference above, the 2 models (SR-8230 and SR-8230S) are completely the same in all the other mechanical and circuit design.

Fig.1 SR-8230 Portable X-ray Unit

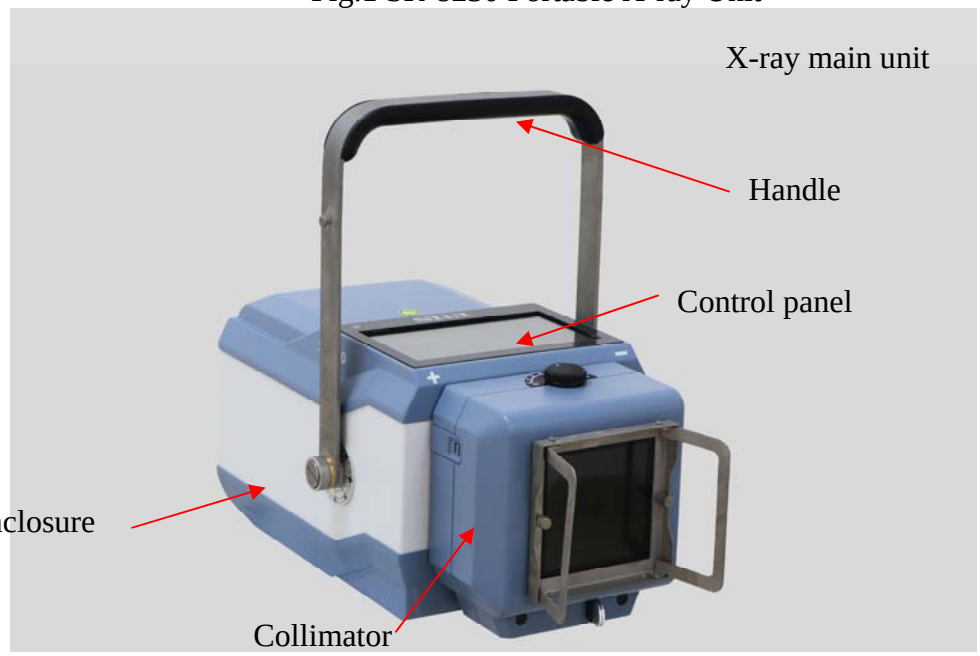

Fig.2 SR-8230S Portable X-ray Unit

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 X-ray unit. 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 device can be used with an X-ray flat panel detector, a computer for receiving and detecting signal results and an image processing software. The portable X-ray unit SR-8230 /SR-8230S is designed for handheld or stand-mounted imaging. The portable X-ray unit SR-8230 / SR-8230S can be configured to an optional portable stand/rack (see Fig. 3) or use a stand that complies with IEC 60601- 1 safety standard. The recommended maximum load that the stand can safely carry is 30kgs to ensure the mechanical stability and effectiveness of the device.

Fig. 3

5.5 Indications for Use

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 for mammography.

5.6 Comparison of Technological Characteristics with the Predicate Device

The comparison between the overall specifications of predicate device (TR90BH) and the new device (SR-8230/SR-8230S) is shown in Table 1, and the comparison between the Collimator specifications of reference device (JADE Mobile X-ray) and the new device (SR-8230/SR-8230S) 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.

Table 1 Subject and Predicate (TR90BH) Device Comparison

Description	Subject Device SR-8230/SR-8230S	Predicate Device TR90BH (K182207)
Indications for use	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 for mammography.	The TR90BH is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. Not to be used on bariatric patients, unless imaging body extremities Not for mammography use. The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

Description	Subject Device SR-8230/SR-8230S	Predicate Device TR90BH (K182207)
Comment on Indications	Original Indications	Certain limitations apply because of the lower maximum kVp output as compared to the predicate and because of the possibility of handheld use on extremities. See indications above.
Weight	15kgs(33.06lb) (Including Collimator)	7.5kgs(16.53lb) (Including Collimator)
Size	460mm×245mm×188mm	219 mm x 442 mm x 190 mm
Energy Source	Lithium-ion Rechargeable Battery（44.4V DC), 300 exposures per charge	Lithium-ion Rechargeable Battery (57.6VDC), 300 exposures per charge.
Use Interface	SR-8230: Soft touch push buttons SR-8230S: Touch screen	Soft touch push buttons
Exposure time	0.02 sec – 6.3 sec: R'10 sec Step	0.01sec – 1.0 sec :0.01 sec Step High Power Mode 0.01 sec – 0.3 sec:0.01 sec Step
Memory Settings (technique)	16 memories	5 memories
HF Generator	High Frequency	High Frequency
kW	5.0kW	1.35kW
kVp	40-125kVp	40-90kVp

Description	Subject Device SR-8230/SR-8230S	Predicate Device TR90BH (K182207)
mA	10mA-100mA: R'10 sec Step	20 mA @ 40kVDC – 60kVDC (2kVP steps) 15 mA @ 62kVDC – 80kVDC (2kVP steps) 10 mA @ 82kVDC – 90kVDC (2kVP steps) High Power Mode 15 mA @ 82kVDC – 90kVDC (2kVP steps) 0.02Comment: 90 kVP maximum instead of 120 kVP maximum.
FDA Performance Standard	Complies	Complies
Collimator	SIUI SR-8200-39L	Mikasa BLD34L

Table 2 Subject and **Reference Device** (JADE-32) Comparison

Description	Subject Device SR-8230/SR-8230S	Reference Device JADE-32 (K183388)
Output Rating	Max. 5.0kW(40mA@125kV)	Max. 3.2kW(40mA@ 80kV, 32mA@100kV,25mA@120kV)
Type	Microprocessor controlled High Frequency inverter	Microprocessor controlled High Frequency inverter
kV Range	40~125kV,86 Step (1kV Step)	40~120kV,81 Step (1kV Step)
mA Range	10~100mA,11 Steps (10,12.5,16,20,25,32,40,50,64,80,100mA)	10~80mA, 10 Step (10,12.5,16,20,25,32,40,50,64,80 mA)
Exposure Time	0.02~6.3seconds, 26 Step (in 25% Steps)	0.01~10 seconds, 21 Step (in 25% Steps)
mAs Range	0.4~200mAs, 28 Step (in 25% Steps)	0.1~250mAs, 35 Step (in 25% Steps)

Description	Subject Device SR-8230/SR-8230S	Reference Device JADE-32 (K183388)
X-ray Tube Type	Stationary Anode	Stationary Anode
Focal Spot Size (Small/Large)	0.6/1.8mm	0.5/1.5mm
Anode Heat Storage Capacity	42,000HU (30,000J)	56,000HU (40,000J)
Power Cord Length	3m	5m
Exposure Hand-switch Cord Length	6m (Max. Length)	5m (Max. Length)
X-ray switching frequency	100kHz	100kHz
Control	2 Point Control (kV, mAs)	2 Point Control (kV, mAs)
Anatomical Programs	Preprogrammed 16 APR data- User Programmable	Preprogrammed 9 APR data- User Programmable

Table 3 Collimator Specs Comparison

Description	Subject Device SIUI SR-8230/SR-8230S	Reference Device DRGEM JADE Mobile X-Ray System (K183388)
Model	SR-8200-39L	KM1
Manufacturer	SIUI	DRGEM
Control	Manual with 15, 30, 45, 60sec. Lamp timer	Manual with 15, 30, 45, 60sec. Lamp timer
Field Shape	Rectangular	Rectangular
Max. Field Size	44x44cm (at 100cm SID)	44x44cm (at 100cm SID)
Leakage Radiation	< 40mR/hr. (at SID 1m)	< 40mR/hr. (at SID 1m)
Max. kVp shield	150kV	150kV

Description	Subject Device SIUI SR-8230/SR-8230S	Reference Device DRGEM JADE Mobile X-Ray System (K183388)
Inherent Filtration	1.2mmAl eq.	2.0mmAl eq.
Light source	9W LED	19W LED
Standard	Rotating flange	Rotating flange
Option	Tape measure (Max.200cm)	Tape measure (Max.200cm)
Electrical Rating	3-12VDC,10W	12 – 45VDC, 20W
Dimension/weight	170(W)×180(D)×105(H) mm / 1.2kg(2.65lb)	172(W)×172(D) ×97(H)mm / 2.5kg(5.51lb)

5.7 Non-clinical Testing Summary

The SR-8230/SR-8230S Portable X-ray Unit complies with and/or was tested in accordance with the following FDA guidance and International Standards:

- IEC 60601-1: 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: 2015 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: 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
- ISO 10993-5:2009 Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Tests for irritation and delayed-type hypersensitivity
- IEC 62304:2006+AMD1:2015 Medical device software – Software life-cycle

processes

- IEC 60601-1-6:2015 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 Quality management for medical devices
- Guidance for the Content of Premarket Submissions for Software Contained in 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. 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.

5.8 Software Description

The system control software of SR-8230/SR-8230S 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 X-ray unit. 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 Level of Concern for the Software Device is Moderate.

5.9 Clinical Testing

Clinical testing is not necessary for the SR-8230/SR-8230S Portable X-ray unit in order to demonstrate substantial equivalence to the predicate device.

5.10 Conclusion

The subject device SR-8230/SR-8230S 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-8230/SR-8230S is higher. The SR-8230/SR-8230S can be used for imaging including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities, and the predicate device TR90BH can be used for imaging of head, abdomen, extremities and chest. Compared with TR90BH, the SR-8230/SR-8230S can be used for additional imaging of cervical spine, lumbar spine and pelvis. In terms of safety, the exposure conditions and radiation doses used for X-ray exams of cervical spine, lumbar spine and pelvis are equivalent to the parameters and radiation doses required for head, abdomen, extremities and chest exams, which is not intended to increase risks of user safety; In terms of effectiveness, the clinical images of bone and soft tissues of the subject device can address doctor's diagnostic requirements for the sites. Nevertheless, it does not affect the safety and effectiveness of the SR-8230/SR-8230S, nor does it change the indications for use of the SR-8230/SR-8230S unit.

The indications for use of the SR-8230/SR-8230S Portable X-ray Unit 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.