January 6, 2025

Shenzhen SONTU Medical Imaging Equipment Co., Ltd.
℅ Mike Gu
RA Director
Room 1001, Building 19, No. 3188 Renming Road
Suzhou, Jiangsu 215031
CHINA

Re: K242499
Trade/Device Name: Digital Radiography X-ray System (SONTU100-RAD (E), SONTU300-Mars (E))
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: August 15, 2024
Received: December 6, 2024

Dear Mike Gu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
Diagnostic X-Ray Systems Team
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)*
K242499

Device Name
Digital Radiography X-Ray System (Sontu100-Rad(E), Sontu300-Mars(E))

Indications for Use *(Describe)*

The Digital radiography X-ray system is used in hospitals, clinics, and medical practices.
The Digital radiography X-ray system enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. It is not intended for mammographic applications.
The Digital radiography X-ray system uses digital detectors for generating diagnostic images by converting X-rays into image signals.

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

Submission: K242499

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Sponsor Identification

Shenzhen SONTU Medical Imaging Equipment Co.,LTD
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Date prepared July 30, 2024

2. Designated Submission Correspondent

Mr. Mike Gu (Primary Contact Person)
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3. DEVICE

Device Name: Digital Radiography X-ray System (Sontu100-Rad(E), Sontu300-Mars(E))
Common name: Stationary x-ray system
Regulation number 21 CFR 892.1680
Regulation Class: Class II
Product Code: KPR, MQB

4. PREDICATE DEVICE

Device Name: Digital Radiography X-ray System (K220919, MULTIX Impact E VB10
K213700, MULTIX Impact (VA21))

Common name: Stationary x-ray system

Regulation number 21 CFR 892.1680

Regulation Class: Class II

Product Code: KPR, MQB

5. DEVICE DESCRIPTION

The Digital Radiography X-ray System is a radiography X-ray system. It is designed as a modular system with components such as a ceiling suspension with an X-ray tube, Bucky wall stand, Bucky table, X-ray generator, portable wireless, and fixed integrated detectors that may be combined into different configurations to meet specific customer needs. Software is of Basic level of concern, which is also based on a predicate device.

Table 1 Product models

System	Model
Digital Radiography X-ray System	SONTU100-RAD(E) including SONTU100-RAD(E)-A, SONTU100-RAD(E)-B, SONTU100-RAD(E)-C
	SONTU300-Mars(E) including SONTU300-Mars (E)-A, SONTU300-Mars (E)-B, SONTU300-Mars (E)-C

Table 2 X-ray detector model

Model	Wireless/ wire	Automated Exposure Control function (AEC)	New or based on a predicate device
SONTU50-4343S-C	Wire	Yes	Based on a predicate device
SONTU50-4343W-C	Wireless	Yes	Based on a predicate device
SONTU50-4336W-C	Wireless	Yes	Based on a predicate device
SONTU50-4336S-C	Wire	yes	Based on a predicate device

6. INDICATIONS FOR USE

The Digital radiography X-ray system is used in hospitals, clinics, and medical practices.

The Digital radiography X-ray system enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. It is not intended for mammographic applications.

The Digital radiography X-ray system uses digital detectors for generating diagnostic images by converting X-rays into image signals.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is the same as the predicate device in the intended use, material,

biocompatibility, and similar in product style, design feature and dimension. So the subject device is similar to the predicate device.

Table 2: Comparison of the Digital Radiography X-ray System SONTU100-RAD(E) to the predicate device.

ITEM	Proposed Device	Predicate Device K220919	Remark
Trade Name	Digital Radiography X-ray System	Stationary x-ray system	/
Model	SONTU100-RAD(E)	MULTIX Impact E	/
Product Code	KPR, MQB	KPR, MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
Class	II	II	Same
Indications for Use	The Digital radiography X-ray system is used in hospitals, clinics, and medical practices. The Digital radiography X-ray system enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. It is not intended for mammographic applications. The Digital radiography X-ray system uses digital detectors for generating diagnostic images by converting X-rays into image signals.	MULTIX Impact E is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact E enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and obese patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact E uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact E is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes. MULTIX Impact E is not intended for mammography.	Same SONTU100-RAD(E) covers the same target population for adult and bariatric patients as compared to the predicate device but excludes the pediatric. Safety and effectiveness of the system remains same as compared to the predicated device for stationary x-ray system.
Generator	50KW high frequency X-ray Generator with line voltage 3-phase, 380V (50/60Hz) and with line voltage 1- phase, 220V/110V (50/60Hz)	50KW high frequency X-ray Generator with line voltage 3-phase, 380V / 400V / 440V (50/60Hz), 480 V (60Hz)	Same. The line voltage 3- phase of Predicate Device covers the range of Proposed Device, this difference doesn't raise the issue of the product's safety and effectiveness. For the line voltage 1- phase, voltage, current, Current time product, and exposure time, the proposed device has been tested and verified about the electrical safety according to IEC 60601-
	NA	40KW high frequency X-ray Generator with line voltage 1-phase, 208-230V /(50/60Hz)	
	Voltage:40kV~150kV Current:10mA~630mA Current time product:0.1mAs~1000mAs Exposure time:1ms~10000ms	Voltage:40kV~150kV Current:Max 50A Current time product:50 kW: 0.5 mAs to 800 mAs	

			1:2005+A1:2012+A2:2020, IEC 60601-1-3:2008+A1:2013+A2:2021, IEC 60601-2-28:2017 and IEC 60601-2-54:2022. EMC test also has been conducted according to IEC 60601-1-2:2020. This difference does not affect the safety and effectiveness of the product.
X-ray Tube	LQ 16 tube with following key performance: -Heat capacity of anode: 212KJ (300kHU) -Input Power with Ref.355W:54KW -Anode rotary frequency: 50/60 Hz (2800/3200 rpm) E7843X tube with following key performance: -Heat capacity of anode: 111KJ (150kHU) -Input Power with Ref.142W:50KW -Anode rotary frequency: 50/60 Hz (2700/3200 rpm) E7252X tube with following key performance: -Heat capacity of anode: 210KJ (300kHU) -Input Power with Ref.142W:44.6KW -Anode rotary frequency: 50/60 Hz (2700/3200 rpm)	RAY-12_3S tube with following key performance: -Heat capacity of anode: 170KJ (230kHU) -Input Power with Ref.300W: 54KW -Anode rotary frequency: 50/60 Hz (3000/3600 rpm)	Similar. LQ 16 and E7252X have more heat capacity of anode heat capacity means it can continuous exposure of more images or exposure under higher conditions. So-the proposed device is more clinically-beneficial than Predicate Device. Performance for E7843X reduced for lower cost and low-end market. Proposed Device provides more options for market needs. This difference does not affect the safety and effectiveness of the product
Collimator	Manual collimator with feedback following information to system: -Blade positions	Manual collimator with feedback following information to system: -Blade positions -Cu filter status	Similar. Proposed Device's collimator reduced Configuration for lower cost and low-end market. The collimator with system has been tested and verified about the electrical safety according to IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-3:2008+A1:2013+A2:2021, and IEC 60601-2-54:2022. Verification and Validation testing concluded no impact on safety and effectiveness.
Detector	SONTU50-4343S-C SONTU50-4343W-C SONTU50-4336W-C	Wireless detector: Mars1717VS	Similar, Proposed Device's detector was tested compared with

	SONTU50-4336S-C		Predicate Device's detector, verification and validation testing concluded Proposed Device's detector is equivalent to Predicate Device's detector 's detector. All the flat panel detectors have been tested with system. The system has been tested and a risk analysis performed. There is "No negative impact on safety or efficacy" and no new potential or increased safety risks concerning were raised because of this difference.
Floor mounted tube stand	Table mounted tube stand Integrated fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting	Integrated fully manual TS - Manual tube tilting - Manual longitudinal movement - Manual tube lifting	Same
Automatic Exposure Control (AEC)	3 fields AEC chamber with analog interface to system	3 fields AEC chamber with analog interface to system	Same
Patient Table	Fixed table with integrated rail mounting tube stand	Fixed table with integrated rail mounting tube stand	Same
Human Machine Interface (HMI)	Tube-side control module (TCM) with following functions: -SID display -Tube angle display -Release brakes	Tube-side control module (TCM) with following functions: -SID display -Tube angle display -Release brakes	Same Configuration reduced for lower cost and low-end market. This difference does not affect the safety and effectiveness of the product.
	N/A	Touch User Interface module (TUI)	

Table 3 Comparison of the Digital Radiography X-ray System SONTU300-Mars(E) to the predicate device.

ITEM	Proposed Device	Predicate Device K213700	Remark
Trade Name	Digital Radiography X-ray System	Stationary x-ray system	/
Model	SONTU300-Mars(E)	MULTIX Impact;	/
Product Code	KPR, MQB	KPR, MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
Class	II	II	Same
Indications for Use	The Digital radiography X-ray system is used in hospitals, clinics, and medical practices. The Digital radiography X-ray	MULTIX Impact is a radiographic system used in hospitals, clinics, and medical practices. MULTIX Impact	Similar SONTU300-Mars(E) covers the same target population for adult and

	system enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. It is not intended for mammographic applications. The Digital radiography X-ray system uses digital detectors for generating diagnostic images by converting X-rays into image signals.	enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. Exposures may be taken with the patient sitting, standing, or in the prone position. MULTIX Impact is not intended for mammography. MULTIX Impact uses digital detectors for generating diagnostic images by converting X- rays into image signals. MULTIX Impact is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	bariatric patients as compared to the predicate device but excludes the pediatric. Safety and effectiveness of the system remains same as compared to the predicated device for stationary x-ray system.
Generator	50KW high frequency X-ray Generator with line voltage 3- phase, 380V (50/60Hz), 50KW high frequency X-ray Generator with line voltage 1- phase, 220V/110V (50/60Hz) Voltage:40kV~150kV Current:10mA~630mA Current time product:0.1mAs~1000mAs Exposure time:1ms~10000ms	Polydoros RFX 56 kW high frequency X-ray Generator with line voltage 3-phase,380 V/400 V/440 V (50/60 Hz)； 480 V (60 Hz) Voltage:40kV~150kV Current:Max 50A Current time product:0.5 mAs to 800 mAs for 55 kW/65 kW 0.5 mAs to 1000 mAs for 80 kW	Similar Output Power of Proposed Device is similar to the predicate device. The line voltage 3- phase of Predicate Device covers the range of Proposed Device, this difference doesn't raise the issue of the product's safety and effectiveness. For the line voltage 1-phase, voltage, current, Current time product, and exposure time, the proposed device has been tested and verified about the electrical safety according to IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-3:2008+A1:2013+A2:2021, IEC 60601-2-28:2017 and IEC 60601-2-54:2022. EMC test also has been conducted according to IEC 60601-1-2:2020. This difference does not affect the safety and effectiveness of the

			product.
X-ray Tube	LQ 16 tube with following key performance: -Heat capacity of anode: 212KJ (300kHU) -Input Power with Ref.355W:54KW -Anode rotary frequency: 50/60 Hz (2800/3200 rpm) E7843X tube with following key performance: -Heat capacity of anode: 111KJ (150kHU) -Input Power with Ref.142W:50KW -Anode rotary frequency: 50/60 Hz (2700/3200 rpm) E7252X tube with following key performance: -Heat capacity of anode: 210KJ (300kHU) -Input Power with Ref.142W:44.6KW -Anode rotary frequency: 50/60 Hz (2700/3200 rpm)	RAY-14S_3F RAY-14S_3F tube with following key performance: -Heat capacity of anode: 260KJ (350kHU) -Input Power with Ref.300W: 78KW -Anode rotary frequency: 150/180 Hz(≈ 8500 to 10800 rpm)	Similar. LQ16, E7843X and E7252X are for lower cost and low-end market. Proposed Device provides more options for market needs.
Collimator	Manual collimator	Manual collimator - Collimator ML03 - Collimator ML04 - Collimator RFU Motorized collimator - Collimator ML04 - Collimator RFU	Same
Detector	SONTU50-4343S-C SONTU50-4343W-C/ SONTU50-4336W-C/ SONTU50-4336S-C	- Trixell Pixium 3543EZH (MAX wi-D) - iRay Mars1717VS (Core XL) - iRay Venu1717X (Core Static)	Similar. Proposed Device's detector was tested compared with Predicate Device's detector, verification and validation testing concluded Proposed Device's detector is equivalent to Predicate Device's detector 's detector. All the flat panel detectors have been tested with system. The system has been tested and a risk analysis performed. There is “No negative impact on safety or efficacy” and no new potential or increased safety risks concerning were raised because of this difference.

Bucky wall stand	Motorized vertical module	Manual or motorized vertical module	Same. The motorized vertical module of the Bucky wall stand is exactly the same for Proposed Device and Predicate Device. For cost reduction reasons, proposed device is not equipped with manual module. This difference does not affect the safety and effectiveness of the product.
	-Motorized vertical module	- Motorized vertical module - Manual tilting module	
X-ray tube stand	Table mounted fully motorized - Motorized tube tilting - Motorized longitudinal - Motorized tube tilting	Floor mounted semi-motorized - - Manual tube tilting - Manual longitudinal movement Floor mounted fully motorized - Manual tube tilting - Motorized tube lifting - Manual longitudinal movement - Motorized tube tilting - Motorized longitudinal	Same The Floor mounted fully motorized of Proposed Device and Predicate Device are identical.
Patient Table	Fixed table with integrated rail mounting tube stand wireless or wired detector.	Elevating patient table with tray for wireless or fixed detector	Similar. Fixed table and Elevating patient table are functionally identical. Fixed table is more cost effective and better suited for the lower end of the market. This difference does not affect the safety and effectiveness of the product.
Human Machine Interface (HMI)	No Smart Remote Control.	Smart Remote Control (SRC) supported by Siemens provided Phone that meets minimum requirements.	Similar. Proposed Device is not equipped with SRC function due to lower cost and low-end market. This difference does not affect the safety and effectiveness of the product.

8. PERFORMANCE DATA

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Digital Radiography X-ray System conforms to the following standards:

- AAMI ES60601-1 IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

- IEC 60601-1-2 2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-28 2017 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC60601-2-54 2022 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- 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 60601-1-6 2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60613:2010 Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis
- IEC 60336:2020 Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics
- ASTM D4169-2022 Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI IEEE USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence

Proposed Sontu50 Flat panel detectors were tested with Effect Image Area, Linear Dose Range, Linear Dynamic Range, Spatial Resolution, Low Contrast Resolution, Flat Uniformity, Modulation Transfer Function, Detective Quantum Efficiency, Artifact, Erasure Thoroughness, which comparing with predicate device, and the comparison test verified that all the performance parameters of flat panel detector meet the requirements, and the performance parameters of proposed detector and predicate detector are the same. Additionally Conducting a concurrence evaluation on a certain number of clinical images from the same phantom or patients and reporting the results. The images are from different sites such as the chest, lumbar spine, elbow joint, knee joint, skull, pelvis, wrist joint, ankle joint, hand, and foot. The results show the ability of the device to provide images with equivalent diagnostic capability to those of the cleared predicate devices.

Software Documentation for a basic Level of Concern software per FDA's Guidance Document Guidance for the Content of Premarket Submissions for Device Software Functions, issued on June 14, 2023, is also included as part of this submission. The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted on the Digital Radiography X-ray System during product development.

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the software specifications have met

the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

9. CLINICAL DATA

See the discussion in Section 8.

10. CONCLUSION

The indications for use statement for the subject device is similar to that of the predicate. The differences between the proposed device and its predicate device do not raise new issues of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Digital Radiography X-ray System should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing described, Shenzhen SONTU Medical Imaging Equipment Co., Ltd. concludes that the Digital Radiography X-ray System is as safe, as effective, and performs as well as the legally marketed as the predicate devices (K213700 and K220919).