November 1, 2024

Shanghai United Imaging Healthcare Co., Ltd.
℅ Gao Xin
Regulatory Affairs Manager
No.2258 Chengbei Rd. Jiading District
Shanghai, 201807
CHINA

Re: K241068
Trade/Device Name: uDR 780i
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: July 8, 2024
Received: September 30, 2024

Dear Gao Xin:

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 Radiological 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)*
K241068

Device Name
uDR 780i

Indications for Use *(Describe)*
The uDR 780i Digital Medical X-ray system is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other anatomic sites. Applications can be performed with the subject sitting, standing, or lying in the prone or supine position. Not 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

1. **Date of Preparation:**
   July 5, 2024
2. **Sponsor Identification**

Shanghai United Imaging Healthcare Co.,Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Establishment Registration Number: 3011015597

Contact Person: Xin Gao
Tel: +86-021-67076888-5386
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3. **Identification of Proposed Device**

Trade Name: uDR 780i
Common Name: Digital Medical X-ray System
Model(s): uDR 780i

Regulatory Information
Classification Name: Stationary X-Ray System
Classification: II
Product Code: KPR
Regulation Number: 21 CFR 892. 1680
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

Predicate Device

510(k) Number: K173953
Device Name: Stationary X-Ray System

Regulatory Information
Classification Name: Stationary X-Ray System
Classification: II
Product Code: KPR
Regulation Number: 21 CFR 892. 1680
Review Panel: Radiology

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5. Device Description:

The uDR 780i is a digital radiography (DR) system that is designed to provide radiography examinations of sitting, standing or lying patients. It consists of the following components: Tube Ceiling Suspension with tube and collimator, Bucky Wall Stand, Elevating Table, High Voltage Generator, wireless flat panel detectors and an acquisition workstation. The system generates images which can be transferred through DICOM network for printing, review and storage.

6. Intended Use Statement:

The uDR780i digital medical X-ray system is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other anatomic sites. Applications can be performed with the subject sitting, standing, or lying in the prone or supine position. Not for mammography.

7. Substantially Equivalent (SE) Comparison

A comparison between the technological characteristics of proposed and predicate devices is provided as below.

Table 1 Comparison of Technology Characteristics

Item	Proposed Device uDR 780i	Predicate Device uDR 780i K173953	Remark
General			
Product Code	KPR	KPR	Same
Regulation No.	892.1680	896.1680	Same
Class	II	II	Same
Intended Use	The uDR 780i Digital Medical X-ray system is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other anatomic sites. Applications can be performed with the subject sitting, standing, or lying in the prone or supine position. Not for mammography.	The uDR 780i Digital Medical X-ray system is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other anatomic sites. Applications can be performed with the subject sitting, standing, or lying in the prone or supine position. Not for mammography.	Same
Specifications			
High Voltage Generator			

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Item	Proposed Device uDR 780i	Predicate Device uDR 780i K173953	Remark
Max. Power/kW	65kW/80kW	65kW/80kW	Same
Max. tube Voltage(kV)	150kV	150kV	Same
Shortest exposure time	1ms	1ms	Same
X-Ray Tube Assemble			
Focus Nominal Value	0.6/1.2	0.6/1.2	Same
Maximum peak voltage	150kV	150kV	Same
Anode Heat Content	65kw: ≥300kHU 80kw: ≥400kHU	65kw: ≥300kHU 80kw: ≥400kHU	Same
Anode Target Angle	12°	12°	Same
X-ray tube assembly Heat content	65kw: ≥1250KHU 80kw: ≥1500KHU	65kw: ≥1250KHU 80kw: ≥1500KHU	Same
Flat Panel Detector			
Configuration of Digital Panels	Battery or DC operated	Battery or AC operated	Note1
Semiconductor material Amorphous silicon (a-Si)	Semiconductor material Amorphous silicon (a-Si)	Semiconductor material Amorphous silicon (a-Si)	Same
Scintillator Cesium iodide (CsI)	Scintillator Cesium iodide (CsI)	Scintillator Cesium iodide (CsI)	Same
specifications	3320x3408 125μm	3320x3408 125μm	Same
Effective radiographic size	41.5cm x 42.6cm	41.5cm x 42.6cm	Same
Collimator			
Inherent filtration	1mm Al	1mm Al	Same
Copper prefilter	without filter, 0.1 mm, 0.2 mm, 0.3 mm;	without filter, 0.1 mm, 0.2 mm, 0.3 mm;	Same
Display			
Specification	≥21inch, ≥ 1080x1920	24inch, 1200x1920	Note2
Standards			
DICOM	DICOM3	DICOM3	Same
Power Source	AC Line, Various voltages available	AC Line, Various voltages	Same

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Item	Proposed Device uDR 780i	Predicate Device uDR 780i K173953	Remark
		available	
Patient Table			
Motorized vertical travel	≥38.2cm	⩾38.2cm	Same
X-ray absorption	< 0.8mmAl	< 0.8mmAl	Same
Tabletop travel	Longitudinal:≥800mm Transverse: ≥250mm	Longitudinal:±40cm Transverse:±12.5cm	Note3
Max. patient weight	320kg	225kg	Note4
Detector travel range	⩾67cm	⩽67cm	Note5
Auto tracking for adjusting the table height is maintained	Yes, X-ray tube follows table height adjustment; source-image distance is maintained.	Yes, X-ray tube follows table height adjustment; source-image distance is maintained.	Same
Auto tracking for longitudinal tube travel	Yes, detector follows tube movement; centering maintained.	Yes, detector follows tube movement; centering maintained.	Same
Auto tracking for tube rotation	Yes, detector follows tube movement; centering maintained.	Yes, detector follows tube movement; centering maintained.	Same
Software function			
Import/Export images	Yes	Yes	Same
Image Search available	Yes	Yes	Same
Image Viewing	Yes	Yes	Same
Image measurement	Yes	Yes	Same
Image Annotation	Yes	Yes	Same
Image Operations	Yes	Yes	Same
Generator	Yes	Yes	Same
Raw image Data processing	Yes	Yes	Same
Post image data processing	Yes	Yes	Same
Safety			
Electrical Safety	ANSI/AAMI ES 60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic	AAMI ANSI ES60601-1:C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment	Note6

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Item	Proposed Device uDR 780i	Predicate Device uDR 780i K173953	Remark
	safety and essential performance	- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	
EMC	Comply with IEC60601-1-2	Comply with IEC60601-1-2	Same
Biocompatibility	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10). Comply with ISO10993-5, ISO10993-10	Same
Clinical	Clinical Image Evaluation for the proposed device are provided in Section 28 Clinical Image Evaluation.		
Justification			
Note ID	Justification		
Note 1	1. The configuration of Digital Panel Detector of predicate device is power by Battery or operate in DC power, but there was an error in the description in the previous submission of K173953; 2. The configuration of Digital Panel Detector of the proposed device and predicate device is the same, which is power by Battery or operate in DC power.		
Note 2	Compare the predicted device, the proposed device has added multiple display options through design changes, and these display specification all meet the requirements.		
Note 3	Compare the predicted device, the proposed device design has not been changed, and a clearer definition of Tabletop travel has been provided to meet the production requirements.		
Note 4	Compare the predicted device, the proposed device has increased the max. patient weight of the Patient Table by design change, make patient table to have better performance.		
Note 5	Compare the predicted device, the proposed device design has not been changed, corrected description error in the predict device.		
Note 6	The proposed device meets the requirement of the latest ANSI/AAMI ES 60601-1 standard.		

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8. Non-Clinical Test Conclusion

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

- ANSI/AAMI ES 60601-1:2005 & A1:2012 & A2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2008+A1:2013+A2:2021 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.
- 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

9. Clinical Image Evaluation

The clinical image evaluation was performed under the proposed device. Sample images of chest, abdomen, spine, pelvis, upper extremity and lower extremity were provided with a board certified radiologist to evaluate the image quality in this submission. Each image was reviewed with a statement indicating that image quality is sufficient for clinical diagnosis.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the technology characteristics of the modified uDR 780i, reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate devices.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, we conclude that the modified uDR 780i Stationary X-Ray Systems are substantially equivalent to the predicate devices. It does not introduce new indications for use, and has the same technological characteristics and does not introduce new potential hazards or safety risks.