October 10, 2024

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

Re: K242515
Trade/Device Name: uDR 380i Pro
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: August 21, 2024
Received: August 23, 2024

Dear Xin Gao:

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)*
K242515

Device Name
uDR 380i Pro

Indications for Use *(Describe)*

uDR 380i Pro is a mobile digital radiography device intended to acquire X-ray images of the human anatomy for medical diagnosis. uDR 380i Pro can be used on both adult and pediatric patient by a qualified and trained operator. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) SUMMARY

K242515

1. Date of Preparation:
August 23, 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
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Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uDR 380i Pro
Common Name: Mobile Digital Medical X-ray Imaging System
Model(s): uDR 380i Pro

Regulatory Information
Classification Name: Mobile X-Ray System
Classification: II
Product Code: IZL
Regulation Number: 21 CFR 892.1720
Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device

Trade Name: uDR 380i Pro
510(k) Number: K222339
Device Name: Mobile Digital Medical X-ray Imaging System
Manufacturer: Shanghai United Imaging Healthcare Co.,Ltd.

Regulatory Information
Classification Name: Mobile X-Ray System
Classification: II
Product Code: IZL
Regulation Number: 21 CFR 892.1720
Review Panel: Radiology

5. Device Description

uDR 380i Pro is a diagnostic mobile x-ray system utilizing digital radiography (DR) technology. It can be moved to different environments for an examination, like emergency room, ICU and ward. It mainly consists of a lifting column – telescopic cantilever frame system, system motion assembly, X-ray System (high voltage generator, x-ray tube, collimator and wireless flat panel detectors which have been cleared in K230175), power supply system and software for acquiring and processing the clinical images.

uDR 380i Pro is intended to acquire X-ray images for both adult and pediatric, especially for person who may not be able to be moved to a traditional RAD room. uDR 380i Pro have been previously cleared by FDA via K222339.

The system offers:

- A 14”×17” or 11”×14” flat panel detector
- A high-power, 32 kW or 50kW generator
- A maneuverable drive system
- X-ray tube-collimator assembly with flexible movement
- Storage for detectors and supplies
- Image Acquisition Workstation with touchscreen user interface

The modifications performed on the uDR 380i Pro (K222339) in this submission are due to the addition of flat panel detectors, including CXDI-710C and CXDI-810C, and CXDI Control Software NE which were cleared in K230175.
The device software is unchanged from the predicate device, except for the addition of CXDI Control Software NE.
The modifications, which do not affect the intended use or alter the fundamental scientific technology of the device.

6. Indications for use

uDR 380i Pro is a mobile digital radiography device intended to acquire X-ray images of the human anatomy for medical diagnosis. uDR 380i Pro can be used on both adult and pediatric patient by a qualified and trained operator. This device is not intended for mammography.

7. Comparison of Technological Characteristics with the Predicate Devices

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

Table 1 Comparison of Technology Characteristics

ITEM	Predicate Device: uDR 380i Pro K222339	Proposed Device: uDR 380i Pro	Remark
Product Code	IZL	IZL	Same
Regulation No.	21 CFR 892.1720	21 CFR 892.1720	Same
Class	II	II	Same
Indications Use	uDR 380i Pro is a mobile digital radiography device intended to acquire X-ray images of the human anatomy for medical diagnosis. uDR 380i Pro can be used on both adult and pediatric patient by a qualified and trained operator. This device is not intended for mammography.	uDR 380i Pro is a mobile digital radiography device intended to acquire X-ray images of the human anatomy for medical diagnosis. uDR 380i Pro can be used on both adult and pediatric patient by a qualified and trained operator. This device is not intended for mammography.	Same
Specifications			
High Voltage Generator			
Maximum Output Power	32kw/ 50kW	32kw/ 50kW	Same
kV Range	40~150kV	40~150kV	Same
mA Range	10~400mA/ 10~560mA	10~400mA/ 10~560mA	Same
mAs Range	0.1-630 mAs	0.1-630 mAs	Same
X-ray Tube			
Anode Heat Content	300kHU	300kHU	Same
Focus Size	0.6/ 1.2	0.6/1.2	Same
Anode Target Angle	14°	14°	Same
Collimator			
Maximum Light Field	43cm × 43cm	43cm × 43cm	Same
Adjustment Method	Manual	Manual	Same
Flat Panel Detector			

Detector Size	14” × 17”/ 11” × 14”	14” × 17”/ 11” × 14”	Same
Scintillator Material	Cesium Iodide	Cesium Iodide	Same
Semiconductor Material	Amorphous Silicon	Amorphous Silicon	Same
Pixel Size	125μm	125μm	Same
DQE	Typical: 58%@3uGy,0.5lp/mm	Typical: 0.58±10%@3uGy,0.5lp/mm (for AR-C3543W&AR-B2735W) Typical:0.58±10%@2.5uGy ,0.5lp/mm (for CXDI-710C & CXDI-810C)	Note 1
MTF	Typical: 63%@1lp/mm Typical: 35%@2lp/mm	Typical: 63%@1lp/mm Typical: 35%@2lp/mm	Same
Anti-scatter Grid			
Grid size	356mm × 445mm	356mm × 445mm	Same
Grid ratio	8:1	8:1	Same
Telescoping Column			
X-ray Tube Assembly RVA	-315° ~+315°	-315° ~+315°	Same
X-Ray Tube Assembly Tilting Range	-30° ~+90°	-30° ~+90°	Same
Battery			
Battery Capacity	2.40kWh	2.40kWh	Same
Image Acquisition Workstation			
Display Size	19”	19”	Same
Disk Size	500GB	≥500GB	Note 2
Software function			
Image Export/Import	Yes	Yes	Same
Image Viewing	Yes	Yes	Same
Image Measurement	Yes	Yes	Same
Image Annotation	Yes	Yes	Same
Image Post-processing	Yes	Yes	Same
Virtual grid	Yes	Yes	Same

Accessory			
Badge Reader	Yes	Yes	Same
Safety			
Electrical Safety	Comply with ANSI/AAMI ES 60601-1	Comply with ANSI/AAMI ES 60601-1	Same
EMC	Comply with IEC60601-1-2	Comply with IEC60601-1-2	Same
Biocompatibility	Comply with ISO10993-5 and ISO10993-10	Comply with ISO10993-5 and ISO10993-10	Same

Justification	
Note ID	Justification
Note 1	DQE Performance is similar. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 2	The disk size of the proposed device is actually a range value, which is only a descriptive update, however the disk size can satisfy its intended use. So it did not raise new safety and effectiveness concerns.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Testing

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. UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

- ANSI/AAMI ES60601-1:2005& A1:2012 & A2:2021 Medical electric for basic safety and essential performance.
- IEC 60601-1-2: 2014+AMD1: 2020，Edition 4.1，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+AMD1: 2013+AMD2: 2021，Edition 2.2， 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, Edition 2.0, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.
- IEC 60601-1-6:2010+AMD1:2013+AMD2: 2020, Editon 3.2, Medical electrical

equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

- IEC 62366-1: 2015+AMD1: 2020, Edition 1.1, Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304: 2006+AMD1:2015, Edition 1.1, Medical device software - Software life cycle processes.
- IEC TS 60601 -4-2:2024 Edition 1.0, Medical electrical equipment - Part 4-2: Guidance a and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Biocompatibility

- ISO 10993-5: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: 2010, Edition 3.0, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Software

- NEMA PS 3.1-3.20(2022): Digital Imaging and Communications in Medicine (DICOM)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Clinical Image Evaluation

The clinical image evaluation was performed under the proposed device with CXDI-710C. Sample image of Head, 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 are sufficient for clinical diagnosis.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uDR 380i Pro was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device has same indications for use, similar performance, equivalence safety and effectiveness as the predicate device.

The differences above between the proposed device and predicate device do not affect the indications for use, technology characteristics, safety and effectiveness. And no issues are raised regarding to safety and effectiveness.

The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.