September 30, 2022

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

Re: K222339
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: July 30, 2022
Received: August 3, 2022

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 (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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222339

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

K222339

1. **Date of Preparation:**
July 30, 2022

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
Position: Regulatory Affairs Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
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

510(k) Number: K191025
Device Name: DRX-Revolution Mobile X-ray System
Manufacturer: Carestream Health, Inc.

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 K170332 and K192632), 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.
The system offers:

- A 14”×17” or 14”×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

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.

ITEM	Predicate Device: DRX-Revolution	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 for Use	The device is designed to perform radiographic x-ray examinations on all pediatric and adult patients, in all patient treatment areas.	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	32kw/ 50kW	Note 1
kV Range	40~150kV	40~150kV	Same
mA Range	25~400 mA	10~400mA/ 10~560mA	Note 2
mAs Range	0.1-320 mAs	0.1-630 mAs	Note 3
X-ray Tube			
Anode Heat Content	300kHU	300kHU	Same
Focus Size	0.6mm/ 1.2mm	0.6mm/ 1.2mm	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	17” × 17”/ 14” × 17”/ 10” × 12”	14” × 17”/ 11” × 14”	Note 4
Scintillator Material	Cesium Iodide	Cesium Iodide	Same
Semiconductor Material	Amorphous Silicon	Amorphous Silicon	Same
Pixel Size	139μm	125μm	Note 5
DQE	Typical: 63%@2.5uGy,0.5lp/mm	Typical: 58%@3uGy,0.5lp/mm	Note 6
MTF	Typical: 61%@1lp/mm Typical: 32%@2lp/mm	Typical: 63%@1lp/mm Typical: 35%@2lp/mm	Note 7
Anti-scatter Grid			
Grid size	350mm × 430mm	356mm × 445mm	Note 8

Grid ratio	8:1	8:1	Same
Telescoping Column			
X-ray Tube Assembly RVA	-180° ~+180°	-315° ~+315°	Note 9
X-Ray Tube Assembly Tilting Range	-20° ~+90°	-30° ~+90°	Note 10
Max. Distance Between Tube Focus and Ground	2058mm	2000mm	Note 11
Min. Distance Between Tube Focus and Ground	724mm	680mm	Note 12
Battery			
Battery Capacity	2.88kWh	2.40kWh	Note 13
Image Acquisition Workstation			
Display Size	19”	19”	Same
Disk Size	500GB	500GB	Same
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 AAMI ES60601-1:2005 +C1;A2: 2012	Comply with AAMI ES60601-1:2005 +C1;A2: 2012	Same
EMC	Comply with IEC60601-1-2:2014	Comply with IEC60601-1-2:2014	Same

Biocompatibility	Comply with ISO10993-5:2009 and ISO10993-10:2010	Comply with ISO10993-5:2009 and ISO10993-10:2010	Same

Justification	
Note 1	The proposed device has two kinds of maximum output. One is same with the predict device, one is larger than the predict device. Larger maximum output power represents better capability at generating higher mA or kV level in X-ray. When operated under the intended use, increasing mA or kV can achieve the same dose/signal level with shorter exposure time. The difference did not raise new safety and effectiveness concerns.
Note 2	The proposed device has two kinds of mA range. One is larger than the predict device. Larger mA range (10~560mA compare to 25~400mA) represents better capability at generating higher mA level in X-ray. When operated under the intended use, increasing mA can achieve the same dose/signal level with shorter exposure time. The difference did not raise new safety and effectiveness concerns.
Note 3	The proposed device has a larger mAs Range than the predict device. Larger mAs Range can meet the clinical demand for high dose exposure of people with larger body thickness. The different range of mAs did not raise new safety and effectiveness concerns.
Note 4	The proposed device does not have a 17” x 17” detector. However, the 14*17 board can cover any parts that need to be inspected, and it is also a size commonly used in clinical practice. The 11” x 14” detector size is larger than 10” x 12”, which allows it to better cover all detection needs of the infant. In addition, the 11" x 14" detector can meet the size of the crib. The different size of detector did not raise new safety and effectiveness concerns.
Note 5	The pixel size of the proposed device is smaller than that of the predict device. Smaller pixel size, better capability at generating higher spatial resolution X-ray images. The different pixel size of detector did not raise new safety and effectiveness concerns.
Note 6	DQE of the proposed device and predict device was test under different condition. Performance is similar. When operated under the intended use, it did not raise new safety and effectiveness concerns.

Note 7	MTF of the proposed device is better than that of the predict device. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 8	The grid size of the proposed device is larger than that of the predict device and can fully cover its detector. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 9	The X-ray tube assembly RVA range of the proposed device is larger than that of the predict device. Larger range, better X-ray tube assembly positioning capability. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 10	The X-ray tube assembly tilting range of the proposed device is larger than that of the predict device. Larger range, better X-ray tube assembly positioning capability. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 11	The maximum distance between the tube focus and ground of the proposed device is shorter than that of the predict device, however the height can satisfy its intended use. So it did not raise new safety and effectiveness concerns.
Note 12	The minimum distance between the tube focus and ground of the proposed device is shorter than that of the predict device. Shorter distance, better X-ray tube assembly positioning capability. When operated under the intended use, it did not raise new safety and effectiveness concerns.
Note 13	The battery capacity of the proposed device is lower than that of the predict device. However, it can satisfy the requirement of clinical use, thus it did not raise new safety and effectiveness concerns.

8. Performance Date

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:

Electrical Safety and Electromagnetic Compatibility (EMC)

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electric for basic safety and essential performance

(IEC 60601-1:2005, MOD).

- IEC 60601-1-2: 2014, Edition 4.0, 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, Edition 2.1, 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: 2009 +A1:2015+A2:2018, Edition 1.2, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.
- IEC 60825-1: 2007+COR1:2008, Edition 2.0, Safety of laser products - Part 1: Equipment classification and requirements.IEC 60601-1-6:2010+A1:2013, Edition 3.1, 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 - Part 1: Application of usability engineering to medical devices
- IEC 62304: 2006+A1:2015, Edition 1.1, Medical device software - Software life cycle processes.

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(2016): 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

Other Standards and Guidance

- ISO 14971: Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation
- FDA guidance, Pediatric Information for X-ray Imaging Device Premarket Notifications.

Performance Verification

- Code of Federal Regulations, Title 21, Part 1020 Performance standards for

ionizing radiation emitting products

Clinical Image Evaluation

The clinical image evaluation was performed under the proposed device. 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.

9. Conclusions

Based on the comparison and analysis above, the proposed device uDR 380i Pro has the equivalent intended use, safety and effectiveness as the predicate device Carestream DRX-Revolution. The differences in technical specifications between the proposed device and the predicate devices do not negatively affect the system's safety and effectiveness. The proposed device uDR 380i Pro is determined to be Substantially Equivalent (SE) to the predicate device Carestream DRX-Revolution.