Shanghai United Imaging Healthcare Co., Ltd.
% Xin GAO
Regulatory Affairs Specialist
No. 2258 Chengbei Rd., Jiading Industrial District
Shanghai, 201807
CHINA

January 26, 2018

Re: K173953
Trade/Device Name: uDR 780i
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 25, 2017
Received: December 27, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173953

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.

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

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510 (k) SUMMARY

1. Date of Preparation:

December 25, 2017

2. Sponsor Identification

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

Establishment Registration Number: Not yet registered or the Number

Contact Person: Xin Gao
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

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

Intended Use Statement:
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.

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.

4. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K133782
Device Name: NOVA FA DR System

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

5. 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:

- ES60601-1:2005(R)2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- IEC 60601-1-3 Edition 2.1 2013-04, 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 Edition1.1 2015-04 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 Edition 2.0 2010-03 Medical electrical equipment –Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

6. Clinical Test Conclusion

Sample clinical images accompanied by dose information and information detailing acquisition protocols and parameters were reviewed by a board certified radiologist with a statement indicating that images are of diagnostic quality.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device uDR 780i	Predicate Device NOVA FA DR System	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.	Sedecal "NOVA FA DR System" is intended for use by 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 body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	Same
Specifications			
High Voltage Generator			
Rated Power/kW	65kW/80kW	50kW/65kW/80kW	Note1
Max. tube Voltage(kV)	150kV	150kV	Same
Shortest exposure time	1ms	1ms	Same
X-Ray Tube Assemble			
Focus Nominal Value	0.6/1.2mm	0.6/1.2mm	Same
Maximum peak voltage	150kV	150kV	Same
Anode Heat Content	300kHU/400kHU	300kHU/400kHU	Same
Anode Target Angle	12°	12°	Same
X-ray tube assembly Heat content	900kJ (1.3MHU) 1111kJ (1.5MHU)	900kJ(1.3MHU) 950kJ(1.33MHU)	Note2
Flat Panel Detector			
Configuration of	Battery or AC operated	Battery or AC operated	Same

Item	Proposed Device uDR 780i	Predicate Device NOVA FA DR System	Remark
Digital Panels			
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	24inch, 1200x1920	19inch, 1024 x 1280	Note3
Standards			
DICOM	DICOM3	DICOM3	Same
Power Source	AC Line, Various voltages available	AC Line, Various voltages available	Same
Patient Table			
Motorized vertical travel	38.2cm	40cm	Note4
X-ray absorption	≤0.8mmAl	≤1mmAl	Note5
Tabletop travel	Longitudinal:±40cm Transverse:±12.5cm	Longitudinal:+50cm, -60cm Transverse:±12cm	Note6
Max. patient weight	225kg	350kg	Note7
Detector travel range	≤67cm	≤60cm	Note8
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

Item	Proposed Device uDR 780i	Predicate Device NOVA FA DR System	Remark
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	AAMI ANSI ES60601-1:C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Comply with IEC60601-1	Same
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).	Comply with ISO10993-5, ISO10993-10	Same
Justification			
Note ID	Justification		
Note 1	The proposed device does not have rated power of 50kW compare with the predicate device. However, the all clinical application can be achieved under 65kW and 80kW, which the predicate device also has. Therefore, this difference does not affect safety and effectiveness in digital		

Item	Proposed Device uDR 780i	Predicate Device NOVA FA DR System	Remark
	radiography.		
Note 2	The heat content of tube assembly determines the continuous exposure time but not affect the image quality, which does not affect safety and effectiveness in digital radiography.		
Note 3	The display with big size is user friendly for the users, which does not affect the safety and effectiveness in digital radiography.		
Note 4	The small difference in table height affects the user experience but not the clinical application. So it is not affect safety and effectiveness.		
Note 5	The x-ray absorption of the table top should as small as possible, it will optimize the image quality. So it is not affect safety and effectiveness.		
Note6	The top travel range affect the user experience but not the clinical application, and the travel range of uDR 780i is enough for the radiography on adults. So it is not affect safety and effectiveness.		
Note7	The Max. Patient weight (225kg) is enough to satisfy the radiography in most patients, which is not affect the safety and effectiveness.		
Note8	The detector travel range affect the user experience, the grater the range the better user experience, which is not affect safety and effectiveness.		

Substantially Equivalent (SE) Conclusion

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

The differences above between the proposed device and predicate device do not affect the intended 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.