June 27, 2018

Shanghai United Imaging Healthcare Co.,Ltd.
Shumei Wang
Qm&ra VP
No. 2258 Chengbei Rd., Jiading Industrial District
SHANGHAI, 201807 CHINA

Re: K181413
Trade/Device Name: uDR 592h, uDR 596i
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: May 25, 2018
Received: May 30, 2018

Dear Shumei Wang:

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); 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 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,

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)*
K181413

Device Name
uDR 592h, uDR 596i

Indications for Use *(Describe)*
The uDR 592h, uDR596i Radiographic system is intended to 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, limbs and trunk .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

June 22, 2018

2. Sponsor Identification

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

Contact Person: Shumei Wang
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3. Identification of Proposed Device

510(k) Number: K181413
Trade Name: uDR 592h, uDR 596i
Common Name: Digital Medical X-ray System
Model(s): uDR 592h, uDR 596i

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

4. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K132934
Device Name: Multix Select DR
Manufacturer: SIEMENS

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

Reference Device

510(k) Number: K133693
Device Name: DIGITAL RADIOGRAPHY CXDI-401C Wireless
Manufacturer: Cannon.Inc.

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

5. Device Description:

The uDR 592h, uDR 596i is a digital medical X-ray imaging system that the X-ray generated by the X-ray tube assembly is converted into digital signal through flat panel detector, finally image data using TCP/IP protocol transfers to image process software.

The system consists of Bucky Wall Stand, Tube Stand, Table, High-voltage Generator, X-ray Tube Assembly, Collimator, Flat Panel Detector, Power Distribute Unit, Control Console, Pluggable Grid, Ionization Chamber, Stitching Stand, Image Processing System and Monitor. The system software is a program used for patient administration, acquisition and post processing, image transmission and filming.

The system software provides functions such as import/export images, image viewing, image annotation, patient and study administration, store/delete/rec-over rejected images, exposure index monitoring, image documentation and achieving, automatic exposure control (AEC), stitching.
For automatic exposure control function, high voltage generator can terminate exposure automatically and the stitching provided in uDR 596i can stitch 2-4 single frame images into a full image.

This proposed device includes two models: uDR 592h, uDR 596i.
The differences between the two models are as follows:

Spec. / Model	HVG Power	Maximum X-Ray Tube Assembly Heat Content	Maximum Tube Current
uDR 596i	65kW	900kJ (1.25MHU)	800 mA
uDR 592h	65KW	900kJ (1.25MHU)	800 mA
	50KW	975KJ（1354kHU）	630mA

6. Indications for Use

The uDR 592h, uDR 596i Radiographic system is intended to 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, limbs and trunk .Not for mammography.

7. Comparison of Technological Characteristics with the Predicate Devices

The uDR 592h, uDR 596i digital medical X-ray imaging system has the same indications for use as the predicate device Multix Select DR. The fundamental scientific technology of the proposed device is same as the predicate device.

Table 1 below provides a comparison of the technological characteristics and software functions of the proposed device in comparison to the predicate device.

Table 1 Comparison of Technological Characteristics

ITEM	Predicate Device Multix Select DR (K132934)	Proposed Device uDR 592h, uDR 596i (K181413)	Remark
Specifications			
High Voltage Generator			
Rated Power/kW	55kW	50kW for uDR 592h 65kW for uDR 592h and uDR 596i	Note 1
Max. tube Voltage(kV)	133kV	150kV	Note 2
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	133kV	150kV	Note 3
Anode Heat Content	230kHU	230kHU for uDR 592h 300kHU for uDR 592h and uDR 596i	Note 4
Anode Target Angle	12°	12°	Same
X-ray tube assembly Heat content	2240kJ(3MHU)	900k（1.3MHU）	Note 5
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,	Note 6
Display			
Size and Resolution	19inch, 1024 x 1280	24inch, 1200x1920	Note 7
Standards			

ITEM	Predicate Device Multix Select DR (K132934)	Proposed Device uDR 592h, uDR 596i (K181413)	Remark
DICOM	DICOM3	DICOM3	Same
Power Source	AC Line, Various voltages available	AC Line, Various voltages available	Same
Patient Table			
Table height	75cm	68cm	Note 8
X-ray absorption	≤1.2mmAl	≤0.7mmAl	Note 9
Tabletop travel	Longitudinal: ±46cm Transverse: ±12.5cm	Longitudinal: ±50cm Transverse: ±12cm	Note 10
Max. patient weight	200kg	200kg	Same
Detector travel range	≥57.5cm	≥50cm	Note11
Software functions			
Import/Export images	Yes	Yes	Functional Equivalent
Image Viewing	Yes	Yes	Functional Equivalent
Image Annotation	Yes	Yes	Functional Equivalent
Patient and study administration	Yes	Yes	Functional Equivalent
Store/delete/Rec-over rejected images	Yes	Yes	Functional Equivalent
Exposure Index monitoring	Yes	Yes	Functional Equivalent
Image documentation and achieving	Yes	Yes	Functional Equivalent
Automatic exposure control	Yes	Yes	Functional Equivalent
Stitching	No	Only Yes for uDR 596i	Note 12

Justification	
Note ID	Justification
Note 1	The generator (50kW) can satisfy the needs of radiation dose in clinical application. The generator (55kW) can be replaced with generator (65kW) in clinical application, which is not affect safety and effectiveness.
Note 2	Max. tube Voltage determines the highest X-ray quality, which does not affect safety and effectiveness in digital radiography.
Note 3	The peak voltage (133/150kV) can satisfy the standards IEC 60613.
Note 4	The heat content of anode determines the continuous exposure time but not affect the image quality, which does not affect safety and effectiveness in digital radiography.
Note 5	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 6	The filter (0.1mm 0.2mm Al) is enough to satisfy the radiography in most clinical application, which does not affect the safety and effectiveness.
Note 7	The display with big size is user friendly for the users, which does not affect the safety and effectiveness in digital radiography.
Note 8	The small difference in table height affects the user experience but not the clinical application. So it does not affect safety and effectiveness.
Note 9	The x-ray absorption of the table top should as small as possible; it will optimize the image quality. So it does not affect safety and effectiveness.
Note 10	The top travel range affect the user experience but not the clinical application, and the travel range of uDR 592h/uDR 596i is enough for the radiography on adults. So it does not affect safety and effectiveness.
Note11	The detector travel range affect the user experience, the grater the range the better user experience, which does not affect safety and effectiveness.
Note 12	This function has been covered by software requirement specifications, and the testing results show that the function has met the acceptance criteria. The clinical images of stitching feature have been reviewed by a board-certified radiologist, and it is indicated that the provided images are of sufficient diagnostic quality.

Table 2 Comparison of Technology Characteristics for Flat Panel Detector

Model	**Canon AS-401C（K133693）**	**Mars1717XU-VSI (K181413)**	**Remark**
Application	General Radiography	General Radiography	Same
Scintillator material	Scintillator Cesium iodide (CsI)	Scintillator Cesium iodide (CsI)	Same
External Dimensions	460 x 460 x 15.4 mm	460 x 460 x 15.4 mm	Same
Installation Type	Wireless, Portable	Wireless, Portable	Same
Readout Mechanism	Thin Film Transistor	Thin Film Transistor	Same
Pixel pitch	125μm	139μm	Note 13
Active Image Area	41.5cm×42.6cm	42.7cm×42.7cm	Note 14
Pixels	3320×3408	3072×3072	Note 15
ADC Digitization	16bit	16bit	Same
DQE (Typical values)	0.6 at 0 lp/mm	0.65 at 0 lp/mm	Note 16
MTF	0.35 at 2 lp/mm	0.35 at 2 lp/mm	Same
Communication	Wireless: IEEE 802.11n(2.4GHz/5GHz)	Wireless: IEEE 802.11a/b/g/n(2.4GHz/5GHz)	Note 17
Cooling	Air cooling	Air cooling	Same
Weight	3.8Kg	3.8Kg	Same

Justification	
Note ID	Justification
Note 13	139μm is the mainstream Pixel pitch of DR detectors, which does not affect the safety and effectiveness in digital radiography.
Note 14	Large effective radiographic size is convenience for positioning patient and exposure to big parts.
Note 15	Pixels do not affect the safety and effectiveness in digital radiography.
Note 16	Higher DQE does not affect the safety and effectiveness in digital radiography.
Note 17	Support more communication protocol, does not affect the safety and effectiveness in digital radiography.

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including dosimetry and image performance tests were conducted for the uDR 592h, uDR 596i during the product development.

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

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the uDR 592h, uDR 596i in accordance with the following standards:

- ES 60601-1:2005(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
- IEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

Performance Verification

- Clinical Evaluation for sample clinical images evaluation;
- AEC Test Report.

Software

- NEMA PS 3.1-3.20(2011): Digital Imaging and Communications in Medicine (DICOM)
- IEC 62304: Medical Device Software - software life cycle process
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

Biocompatibility

- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Other Standards and Guidances

- ISO 14971: Medical Devices – Application of risk management to medical devices
- Code of Federal Regulations, Title 21, Part 820 - Quality System Regulation
- Code of Federal Regulations, Title 21, Subchapter J - Radiological Health
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)

Software Verification and Validation

Software documentation for a Moderate Level of Concern software per FDA' Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as a part of this submission.

The risk analysis was completed and risk control was implemented to mitigate identified hazards. The testing results show that all the software specifications have met the acceptance criteria. Verification and validation testing of the proposed device was found acceptable to support the claim of substantial equivalence.

UNITED IMAGING HEALTHCARE conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modification, misuse or denial of use, or unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" is included in this submission.

Clinical Testing

No Clinical Study is included in this submission.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uDR 592h, uDR 596i was found to have a safety and effectiveness profile that is similar to the predicate device.

9. Conclusions

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.