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

September 12, 2019

Re: K192293
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: MQB, KPR
Dated: August 20, 2019
Received: August 23, 2019

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192293

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

K192293

1. Date of Prepared

August 20, 2019

2. Sponsor Identification

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No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Xin GAO
Position: Regulatory Affairs Specialist
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3. Identification of Proposed Device(s)

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)

510(k) Number: K181413
Device Name: uDR 592h, uDR 596i
Manufacturer: Shanghai United Imaging Healthcare Co.,Ltd.

Regulatory Information
Classification Name: Stationary X-Ray System
Classification: II
Product Code: KPR, 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 software mainly has the following functions:

- Patient Administration: supporting RIS and PACS system, register the emergency patient, dynamic real-time patient information search and display, support the display and ranking of examinations in different statuses;
- Acquisition and post processing: selecting radiography protocol, display and adjust the exposure parameter, image acquisition and image display, provide image processing tools, such as zoom, pan, adjust window width/window level, delete all graphics, annotation and text, rotate, flip, gray invert, pixel lens, ROI zoom, cut, reload and reset;
- Image Transmission and Filming Function: image transmission to PACS server, filming layout, filming preview, life-size filming, DVD burning function, image export and import function, supporting the USB device.

The uDR 592h, uDR 596i have been previously cleared by FDA via K181413.
The modifications performed on the uDR 592h, uDR 596i (K181413) in this submission are due to the addition of an 80kW high voltage generator, x-ray tube and a new grid configuration (130 cm). Meanwhile, patient table and stitching stand have been optimized.

The modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are following:

- Introduce a 80kW high voltage generator and X-ray tube
- Introduce a new grid configuration (focus: 130cm, grid line: 40L/cm, ratio: 8:1)
- Increase the maximum load weight of patient table and stitching stand.

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

Spec. / Model	HVG Power	Maximum Tube Current	Remark
uDR 596i	80kW	1000 mA	New configuration in this submission
	65kW	800 mA	Configuration in previous submission K181413

uDR 592h	80kW	1000 mA	New configuration in this submission
	65kW	800 mA	Configuration in previous submission K181413
	50kW	630 mA	Configuration in previous submission K181413

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. Technological Characteristic

The technology characteristics of the modified uDR 592h and uDR 596i, 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.

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

Table 1 Comparison of Technological Characteristics

ITEM	**Predicate Device uDR 592h, uDR 596i (K181413)**	**Proposed Device uDR 592h, uDR 596i**	**Remark**
Specifications			
High Voltage Generator			
Rated Power	uDR 592h: 50kW, 65kW uDR 596i: 65kW	uDR592h: 50kW, 65kW, 80kW uDR596i: 65kW, 80kW	Note 1
Max. tube Voltage	150kV	150kV	Same
Shortest exposure time	1ms	1ms	Same
X-Ray Tube Assemble			
Focus Nominal Value	0.6mm, 1.2mm	0.6mm, 1.2mm	Same
Maximum peak voltage	150kV	150kV	Same
Anode Heat Content	uDR 592h: 230kHU, 300kHU uDR 596i: 300kHU	uDR 592h: 230kHU, 300kHU, 400kHU uDR 596i: 300kHU, 400kHU	Note 2
Anode Target Angle	12°	12°	Same
X-ray tube assembly Heat content	uDR592h: 1.354 MHU /1.25 MHU	uDR592h: 1.354 MHU /1.25 MHU/1.5 MHU	Note 3

ITEM	Predicate Device uDR 592h, uDR 596i (K181413)	Proposed Device uDR 592h, uDR 596i	Remark
	uDR596i: 1.25MHU	uDR596i: 1.25 MHU/1.5 MHU	
Collimator			
Inherent filtration	1mm Al	1mm Al	Same
Copper prefilter	without filter, 0.1 mm, 0.2 mm	without filter, 0.1 mm, 0.2 mm	Same
Flat Panel Detector			
Flat Panel Detector	Mars1717XU-VSI	Mars1717XU-VSI	Same
Display			
Size and Resolution	24inch, 1200x1920	24inch, 1200x1920	Same
Standards			
DICOM	DICOM3	DICOM3	Same
Power Source	AC Line, Various voltages available	AC Line, Various voltages available	Same
Patient Table			
Table height	68cm	68cm	Same
X-ray absorption	≤0.7mmAl	≤0.7mmAl	Same
Tabletop travel	Longitudinal:±50cm Transverse:±12cm	Longitudinal:±50cm Transverse:±12cm	Same
Max. patient weight	200kg	250kg	Note 4
Detector travel range	≥50cm	≥50cm	Same
Software functions			
Import/Export images	Yes	Yes	Same
Image Viewing	Yes	Yes	Same
Image Annotation	Yes	Yes	Same
Patient and study administration	Yes	Yes	Same
Store/delete/Recover rejected images	Yes	Yes	Same
Exposure Index monitoring	Yes	Yes	Same
Image documentation and achieving	Yes	Yes	Same
Automatic exposure control	Yes	Yes	Same
stitching	Only yes for uDR596i	Only yes for uDR596i	Same

Justification

Note ID	Justification
Note 1	The proposed device provides an additional generator configuration with rated power of 80kW compare with the predicate device. The new generator configuration with rated power of 80kW have the same clinical application with the generators in the predicated device, but it can cover more patients with bigger body size than predicated device. This difference does not affect safety and effectiveness in digital radiography.
Note 2	Compare with the predicate devices, the proposed devices provide an additional tube with anode heat content of 400kHU, which are used to cooperate with the generator configuration of 80KW. This difference does not change the clinical application and does not affect safety and effectiveness in digital radiography.
Note 3	The additional tube has different X-ray tube assembly Heat content compare with predicated devices, which does not change the clinical application and does not affect safety and effectiveness in digital radiography.
Note 4	The patient table has bigger Max. Patient weight in proposed devices than the predicated devices. It can cover more patients with bigger body size than predicated device. This difference does not affect 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

The following testing was conducted on the proposed devices:

- Performance test for uDR 596i (80KW) and uDR 592h (80KW)
- ES 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment Part 1-2: General Requirements for basic safety and essential Performance
- IEC 60601-1-3 Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-54 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

The test results demonstrated that the device performs as expected and thus, it is substantially equivalent to the predicate devices to which it has been compared.

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

Software Verification and Validation

As a Moderate Level of Concern software per FDA' Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", 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.

Clinical Testing

No clinical testing was conducted on the proposed devices.

9. Conclusion

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 592h and uDR 596i 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.