January 3, 2019

Shangai United Imaging Healthcare Co., Ltd.
Shumei Wang
QM & RA VP
No. 2258 Chengbei Rd., Jiading Industrial District
SHANGHAI, 201807 CHINA

Re: K183143
Trade/Device Name: uCT 520, uCT 528
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 14, 2018
Received: November 15, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183143

Device Name

uCT 520, uCT 528

Indications for Use *(Describe)*

The uCT Computed Tomography X-ray System uCT 520/uCT 528 is a computed tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes and indicated for the whole body (including head, neck, vascular).

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.

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UNITED IMAGING

510 (k) SUMMARY

1. Date of Preparation

November 10, 2018

2. Sponsor Identification

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

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3. Identification of Proposed Device

Trade Name: uCT 520, uCT 528
Common Name: Computed Tomography X-ray System
Model(s): uCT 520, uCT 528

Regulatory Information
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

4. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K181414
Device Name: uCT Computed Tomography X-Ray System
Model(s): uCT 530, uCT 550

Regulatory Information
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description:

The uCT 520/uCT 528 is a multi-slice X-ray computed tomography scanner which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system provides the filter back-projection (FBP) algorithm to reconstruct images in DICOM format, which can be used by post-processing applications.
The system consists of the Gantry, X-ray System, Data Management System, Patient Table, Console, Power Supply Cabinet, Image Processing Computer, and Software. The system software is a program used for patient management, data management, X-ray scan control, image reconstruction, and image archive.

A motorized patient table moves the patient through a circular opening in the Gantry. As the patient passes through the Gantry, a source of x rays rotates around the inside of the circular opening. Detectors on the exit side of the patient record the X rays exiting the section of the patient's body being irradiated as an X-ray "snapshot". Many different "snapshots" (angles) are collected during one complete rotation. The data are sent to a computer to reconstruct all of the individual "snapshots" into a cross-sectional image (slice) of the internal organs and tissues for each complete rotation of the source of x rays.

There are two key features of data processing for denoising and reduce metal artifact, which are KARL iterative denoising reconstruction algorithm and MAC Metal artifact correction algorithm.

This proposed device includes two models: uCT 520, uCT 528.The differences between the two models are as follows:

Spec. / Model	Tube anode storage capacity (MHU)
uCT 520	2.0
uCT 528	3.5

6. Indications for Use

The uCT Computed Tomography X-ray System uCT 520/uCT 528 is a computed tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes and indicated for the whole body (including head, neck, vascular).

7. Comparison of Technological Characteristics with the Predicate Devices

The uCT 520/uCT 528 Computed Tomography X-ray system has the same indications for use as the predicate device uCT 530/uCT 550. The fundamental scientific technology of the proposed device is same as the predicate device.

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	Proposed Device uCT 520, uCT 528	Predicate Device uCT 530, uCT 550	Remark
General			
Product Code	JAK	JAK	Same
Regulation No.	21 CFR 892.1750	21 CFR 892.1750	Same
Class	II	II	Same
Intended Use	The uCT Computed Tomography X-ray System uCT520/uCT528 is a computed tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes and indicated for the whole body (including head, neck, vascular).	The uCT Computed Tomography X-ray System uCT530/uCT550 is a computed tomography X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes and indicated for the whole body (including head, neck, vascular).	Same
Specifications			
Scan Regime	Continuous Rotation	Continuous Rotation	Same
Scan Modes	Scout Axial Scan Helical Scan	Scout Axial Scan Helical Scan	Same
Detector Material	Solid-state GOS	Solid-state GOS	Same
Z-plane coverage	22mm	22mm	Same
Size of detector element in Z-plane	0.55mm	0.55mm	Same
Number of element per row	864	864	Same
Number of detector row	40	40	Same
Maximum slices generated per	80 for uCT 520 80 for uCT 528	40 for uCT 530 80 for uCT 550	Note No.1

rotation (multi-slice capability)			
Minimum slice thickness	0.55mm	0.55mm	Same
Maximum sampling rate	Up to 4800 views per 360°	Up to 4800 views per 360°	Same
Tube anode storage capacity	2MHU for uCT 520 3.5MHU for uCT 528	5.3MHU	Note No.2
Maximum cooling rate	336 kHU/min for uCT 520 395 kHU/min for uCT 528	815 kHU/min	Note No.3
Focal spot size	0.7x0.8mm 1.2x1.4mm	0.5x1.0mm 1.0x1.0mm	Note No.4
Power	42kW	50kW	Note No.5
mA Range	10-350mA	10-420mA	Note No.6
kV Settings	70, 80, 100, 120, 140	70, 80, 100, 120, 140	Same
Aperture	700mm	700mm	Same
Rotation speed	Up to 0.75 sec per 360° rotation	Up to 0.5 sec per 360° rotation	Note No.7
Gantry Tilt	± 30°with 0.5 increment	± 30°with 0.5 increment	Same
Scannable range	1600 mm	1700 mm	Note No.8
Horizontal motion range	1930 mm	2180 mm	Note No.9
Table Horizontal Speed	Up to 200mm/sec	Up to 200mm/sec	Same
Vertical motion range	600 mm-950 mm from the floor	480 mm-950 mm from the floor	Note No.10
Vertical speed	Up to 20 mm/sec	Up to 40 mm/sec	Note No.11
Table Horizontal Position accuracy	±0.25mm	±0.25mm	Same
Table Maximum table load	205kg	205kg	Same
Image Spatial Resolution	High mode: 19 lp/cm @ MTF 0% 15.6±1.6 lp/cm @ MTF10% 11.3±1.2 lp/cm @ MTF50%	High mode: ＞20 lp/cm @ MTF 0% 16.5±1.7 lp/cm @ MTF10% 11.5±1.2 lp/cm @ MTF50%	Note No.12
Image Noise	3.0±0.5 HU at 120 kV, 5.5 mm slice thickness, CTDIvol 24.32 mGy for uCT 520	3.0±0.5 HU at 120 kV, 5 mm slice thickness, CTDIvol 28.9 mGy	Note No.13

	3.0±0.5 HU at 120 kV, 5.5 mm slice thickness, CTDIvol 25.95 mGy for uCT 528		
CT Number Display Range	-1024 ~+8191 HU	-1024 ~+8191 HU	Same
Scan Field of View	Up to 500 mm	Up to 500 mm	Same
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	40mm-500mm 40mm-600mm with extend FOV	Same
Image Matrix	Up to 1024 x 1024	Up to 1024 x 1024	Same
Reconstructed slice thickness	0.55mm,1.1mm,2.2mm,5.5mm ,11mm (axial) 0.55-10mm(helical)	0.55mm,1.1mm,2.2mm,5.5m m,11mm (axial) 0.55-10mm(helical)	Same
Pitch	0.1~2.0	0.1~2.0	Same
Maximum continuous exposure time	Up to 100seconds	Up to 100seconds	Same
Safety			
Electrical Safety	Comply with ES60601-1	Comply with ES60601-1	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).	Patient Contact Materials were tested and demonstrated no cytotoxicity (ISO 10993-5), no evidence for irritation and sensitization (ISO 10993-10).	Same
Clinical	Sample clinical image for both proposed and predicate devices are provided in Section 37 Clinical Evaluation. Electronic file for each image are provide in MISC Folder.		
Justification			
Note ID	Justification		
Note 1	With a reconstruction process, 40 slices or 80 slices can be achieved from the 40 rows detector. Provides the smaller slice number in one rotation induces longer scanning time for CT imaging, which does not affect safety and effectiveness.		
Note 2	Tube anode storage capacity is a kind of measurement about the maximum throughput of CT scanner. When an independent scan is implemented, the tube is heated and if the time interval between two independent scans is long enough, the heat can be dissipated timely but for short scan time interval, the heat which has not been dissipated timely should be stored within tube device and thus for the continuous scans (for short scan time intervals), higher storage capacity means that more continuous scan numbers can be supported. However, tube anode storage capacity has no effect on each independent scan.		

Note 3	Maximum cooling rate is a kind of measurement about the maximum throughput of CT scanner. For the continuous scans, higher maximum cooling rate means that the tube heat can be dissipated faster and thus shorter scan time interval and more continuous scan numbers can be supported. However, it has no effect on each independent scan.
Note 4	Focus spot size has effect on image spatial resolution and smaller size is helpful for resolution improvement. However, the image spatial resolution between the two kinds of devices is equivalent substantially.
Note 5	Provides the smaller power output that induces lower ability of x-ray penetration when scanning the object with high BMI with higher possibility of photon starvation, and the safety has been evaluated by the related testing and verification.
Note 6	Provides the smaller mA output that induces lower ability of x-ray penetration when scanning the object with high BMI with higher possibility of photon starvation, and the safety has been evaluated by the related testing and verification.
Note 7	Provides slower rotation speed that induces longer scan time for examination which does not affect safety and effectiveness.
Note 8	A typical CT scan is to scan a specific length of the anatomical structure. 1600mm scannable range capability of the proposed device have satisfied most of size of human anatomical structure. The scannable range difference does not affect safety and effectiveness.
Note 9	The horizontal motion range of the device affects the size of the scanning room, in other words, it will affect site planning. The difference of horizontal motion range does not affect safety and effectiveness.
Note 10	Vertical motion range is decided by device gantry and couch design which does not affect safety and effectiveness.
Note 11	The Vertical speed of proposed device is lower than the predicated device, that only affect expected scanner scan throughput. The vertical difference does not affect safety and effectiveness.
Note 12	Three values of resolution performance are compared, the 0% response of the MTF, 10% response of the MTF, and the 50% response. For some resolution studies, the 10% MTF has more value in relating the numerical performance to visual assessment of resolution. The detectability of the spatial resolution of the proposed device is 0.32mm (15.6 lp/cm @ MTF10%). The detectability of the spatial resolution of the predicate device is 0.30mm (16.5 lp/cm @ MTF 10%). The size of 0.32mm is equivalent to that of 0.30mm in visual assessment of resolution, which does not affect safety and effectiveness.
Note 13	With 120 kV and 5.5mm slice thickness, the image noise for typical head is 3HU on $CTDI_{vol}$ 24.32 mGy & on $CTDI_{vol}$ 25.95 mGy. The image noise level is equivalent substantially considering the proposed device has measured its noise based on the smaller $CTDI_{vol}$ than the Predicate Device.

The proposed device and the predicate device are the same in regard to most of application features.

Table 2 below provides a comparison of the application features of the proposed device in comparison to the predicate device.

Table 2 Comparison of Application Features

Key Items	Proposed Device uCT 520, uCT 528	Predicate Device uCT 530, uCT 550	Remark
Scan Mode	● Scout Scan ● Axial Scan ● Helical Scan ● Contrast enhanced scan ■ Manual scan ■ Timed scan ■ Bolus Tracking ■ TIBT ● Stationary perfusion scan	● Scout Scan ● Axial Scan ● Helical Scan ● Contrast enhanced scan ■ Manual scan ■ Timed scan ■ Bolus Tracking ■ TIBT ● Stationary perfusion scan	Same
Iterative noise reduction	KARL 3D	KARL 3D	Same
	Adaptive Filter	Adaptive Filter	Same
Metal artifact reduction	MAC	MAC	Same
Automatic exposure control (AEC)	uDose	uDose	Same
Fast workflow	uECO Energy-Saving Module	uECO Energy-Saving Module	Same
	Easy-Logic Intelligent Prediction Platform	Easy-Logic Intelligent Prediction Platform	Same

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 uCT 520/uCT 528 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 uCT 520/528 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 60601-2-44 Edition 3.0 2009, Medical Electrical Equipment - Part 2-44: Particular Requirements For The Basic Safety And Essential Performance Of X-ray Equipment For Computed Tomography
- IEC 60601-1-2:2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60825-1 Edition 3.0 2014, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements

Product Particular Standards

- NEMA XR 25-2010, Computed Tomography Dose Check
- NEMA XR 28-2013, Supplemental Requirements For User Information And System Function Related To Dose In CT
- NEMA XR 29-2013, Standard Attributes on CT Equipment Related to Dose Optimization and Management
- 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 61223-3-5 First Edition 2004-08, Evaluation And Routine Testing In Medical Imaging Departments - Part 3-5: Acceptance Tests - Imaging Performance Of Computed Tomography X-ray Equipment

Performance Verification

- Clinical Evaluation for sample clinical images evaluation;
- AEC Test Report for AEC performance study.
- MAC Performance Evaluation 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)
- Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography

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 uCT 520/uCT 528 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.