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

February 25, 2020

Re: K200016
Trade/Device Name: uCT 530, uCT 550
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: January 2, 2020
Received: January 3, 2020

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)*

K200016

Device Name

uCT 530, uCT 550

Indications for Use *(Describe)*

The uCT Computed Tomography X-ray System uCT530/550 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, cardiac (calcium scoring) and 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

February 15, 2020

2. Sponsor Identification

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3. Identification of Proposed Device

Trade Name: uCT 530, uCT 550
Common Name: 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

4. Identification of Predicate Device(s)

Primary 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

Secondary Predicate Device:

510(k) Number: K172135
Device Name: uCT Computed Tomography X-Ray System
Model(s): uCT 760, uCT 780

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 530/uCT 550 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 features 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 530, uCT 550.The differences between the two models are as follows:

Spec. / Model	HV Power	Rotation speed	Minimum slice thickness	Maximum slices generated per rotation
uCT 530	50kW	Up to 0.5 sec per 360° rotation	0.55mm	40
uCT 550	50kW	Up to 0.5 sec per 360° rotation	0.55mm	80

The uCT 530, uCT 550 have been previously cleared by FDA via K181414. The modifications performed on the uCT 530, uCT 550 (K181414) in this submission are due to the addition of the calcium scoring scan function. Meanwhile some component descriptions have been updated. The modifications are listed as follows:

- Indications for use: cardiac (calcium scoring) is stated in this submission.
- Hardware: Vital Signal Module (VSM) hardware is added to the system.
- Software: workflow of Calcium scoring scan is added to the system.
- Component Descriptions:
  - Update the description of DMS frame and detector building block (DBB).
  - Update the description of the console PC' CPU.
  - Update the description of the gantry control PC' CPU.
  - Update the description of the monitor's size.

6. Indications for Use

The uCT Computed Tomography X-ray System uCT 530/550 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, cardiac (calcium scoring) and vascular.

7. Comparison of Technological Characteristics with the Predicate Devices

Table 1 below provides a comparison of the technological characteristics of the proposed device in comparison to the Primary Predicate Device:

Table 1 Comparison of Technological Characteristics

ITEM	Proposed Device uCT 530, uCT 550	Primary Predicate Device: uCT 530, uCT 550 (K181414)	Remark
General			
Product Code	JAK	JAK	Same
Regulation No.	21 CFR 8 92.1750	21 CFR 892.1750	Same
Class	II	II	Same
Intended Use	The uCT Computed Tomography X-ray System uCT 530/550 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, cardiac (calcium scoring) and vascular.	The uCT Computed Tomography X-ray System uCT 530/550 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).	Note 1

Specifications			
Scan Regime	Continuous Rotation	Continuous Rotation	Same
Scan Modes	Scout scan Axial scan Helical scan Contrast enhanced scan Stationary perfusion scan Gating scan	Scout scan Axial scan Helical scan Contrast enhanced scan Stationary perfusion scan	Note 2
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 rotation (multi-slice capability)	40 for uCT 530 80 for uCT 550	40 for uCT 530 80 for uCT 550	Same
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	5.3MHU	5.3MHU	Same
Maximum cooling rate	815 kHU/min	815 kHU/min	Same
Focal spot size	0.5x1.0mm 1.0x1.0mm	0.5x1.0mm 1.0x1.0mm	Same

Power	50kW	50kW	Same
mA Range	10-420mA	10-420mA	Same
kV Settings	70, 80, 100, 120, 140	70, 80, 100, 120, 140	Same
Aperture	700mm	700mm	Same
Rotation speed	Up to 0.5 sec per 360° rotation	Up to 0.5 sec per 360° rotation	Same
Gantry Tilt	± 30°with 0.5 increment	± 30°with 0.5 increment	Same
Scannable range	1700 mm	1700 mm	Same
Horizontal motion range	2180 mm	2180 mm	Same
Table Horizontal Speed	Up to 200mm/sec	Up to 200mm/sec	Same
Vertical motion range	480 mm-950 mm from the floor	480 mm-950 mm from the floor	Same
Vertical speed	Up to 40 mm/sec	Up to 40 mm/sec	Same
Table Horizontal Position accuracy	±0.25mm	±0.25mm	Same
Table Maximum table load	205kg	205kg	Same
Image Spatial Resolution	High mode: ＞20 lp/cm @ MTF 0% 16.5±1.7 lp/cm @ MTF10% 11.5±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%	Same
Image Noise	3.0±0.5 HU at 120 kV, 5 mm slice thickness, CTDIvol 28.9 mGy	3.0±0.5 HU at 120 kV, 5 mm slice thickness, CTDIvol 28.9 mGy	Same
CT Number Display Range	-1024 ~+8191 HU	-1024 ~+8191 HU	Same
Scan Field of View	Up to 500 mm	Up to 500 mm	Same

	600mm with extend FOV	600mm with extend FOV	
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	40mm-500mm 40mm-600mm with extend FOV	Same
Maximum scannable length	1700mm	1700mm	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,11 mm (axial) 0.55-10mm(helical)	0.55mm,1.1mm,2.2mm,5.5mm,11 mm (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
VSM	Operating voltage: 3.7V DC Common-mode rejection [allowed 10V(rms) line-frequency noise]: ≤1mV (p-v RTI) Signal reduction of the injected frequency: ≤20% (0.67Hz ~ 40Hz) System noise: ≤30μV (p-v RTI) Frequency response: 80%~110% Heart rate range: 30bpm~200bpm	Not Applicable	Note 3
Application Features			
Iterative noise reduction	KARL 3D	KARL 3D	Same
	Adaptive Filter	Adaptive Filter	Same
Metal artifact reduction	MAC	MAC	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	Comparing with the predicate device (K181414), the difference of clinical image is due to the addition of calcium scoring scan function. Sample clinical images of calcium scoring scan provided are of diagnostic quality.		
Justification			
Note ID	Justification		
Note 1	The difference in indications for use between the two devices is due to proposed device adds an indicated use for cardiac (calcium scoring). The proposed device supports a prospective ECG-gating axial scanning technique to reduce the artifact of the cardiac motion. ECG gating tests and sample clinical images evaluation of calcium scoring scan showed the proposed device can obtain clinically acceptable calcium scoring images. The difference in indications for use does not affect the safety and effectiveness.		
Note 2	Provide additional gating scan mode compared with predicate device. For the difference, through ECG gating tests and clinical image evaluation, proposed device can obtain clinically acceptable calcium scoring images. The difference of scan modes does not affect the safety and effectiveness.		
Note 3	Provide additional Vital Signal Module (VSM) that can transmit the patient's ECG to the system intended to trigger scan. The difference does not affect the safety and effectiveness.		

Table 2 below provides a comparison of the technological characteristics of the proposed device in comparison to the Secondary Predicate Device.

Table 2 Comparison of Technological Characteristics

ITEM	Proposed Device uCT 530, uCT 550	Secondary Predicate Device uCT 760, uCT 780 (K172135)	Remark
Hardware			
VSM	Operating voltage: 3.7V DC Common-mode rejection [allowed 10V(rms) line-frequency noise]: ≤1mV (p-v RTI)	Operating voltage: 3.7V DC Common-mode rejection [allowed 10V(rms) line-frequency noise]: ≤1mV (p-v RTI)	Same

	Signal reduction of the injected frequency: ≤20% (0.67Hz ~ 40Hz) System noise: ≤30μV (p-v RTI) Frequency response: 80%~110% Heart rate range: 30bpm~200bpm	Signal reduction of the injected frequency: ≤20% (0.67Hz ~ 40Hz) System noise: ≤30μV (p-v RTI) Frequency response: 80%~110% Heart rate range: 30bpm~200bpm	
Scan Mode			
Scout scan	The system supports acquiring and reconstructing image(s) for scout scan including frontal scout, lateral scout, and dual scout.	The system supports acquiring and reconstructing image(s) for scout scan including frontal scout, lateral scout, and dual scout.	Same
Axial scan	The system supports acquiring and reconstructing image(s) for axial scan. During the x-ray exposure, the patient table remains stationary; the table position may be incremented between x-ray exposures to collect data over a longer z axis range.	The system supports acquiring and reconstructing image(s) for axial scan. During the x-ray exposure, the patient table remains stationary; the table position may be incremented between x-ray exposures to collect data over a longer z axis range.	Same
Helical scan	The system supports acquiring and reconstructing image(s) for helical scan. During the x-ray exposure, the patient table is continuously moving along the z axis.	The system supports acquiring and reconstructing image(s) for helical scan. During the x-ray exposure, the patient table is continuously moving along the z axis.	Same
Contrast enhanced scan	The system supports acquiring and reconstructing image(s) for contrast enhanced scan with contrast injection.	The system supports acquiring and reconstructing image(s) for contrast enhanced scan with contrast injection.	Same
Stationary perfusion scan	The system supports acquiring and reconstructing image(s) at multiple time points over the same	The system supports acquiring and reconstructing image(s) at multiple time points over the same	Same

	anatomic location(s) while the patient table remains stationary.	anatomic location(s) while the patient table remains stationary.	
Gating Scan	The system supports controlling the x-ray exposure based on the ECG signal. Calcium scoring axial scan	The system supports controlling the x-ray exposure based on the ECG signal. Calcium scoring axial scan Calcium scoring helical scan Coronary CTA axial scan Coronary CTA helical scan	Note 4
Justification			
Note ID	Justification		
Note 4	The gating scan of proposed device can be covered by the predicate device, there are no additional applications compared to the predicate device and the description difference of two devices does not affect the safety and effectiveness.		

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 530/uCT 550 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 530/550 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 3.2: 2016, 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 2.0 2007-03, 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
- ECG R-Wave Detection Algorithm 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 530/uCT 550 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, same performance, equivalence safety and effeteness as the predicate devices. The differences above between the proposed device and predicate devices do not affect the intended use, the 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 devices.