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

March 12, 2018

Re: K172135
Trade/Device Name: uCT 760, uCT 780
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: July 3, 2017
Received: July 14, 2017

Dear Shumei Wang:

This letter corrects our substantially equivalent letter of March 2, 2018.

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172135

Device Name
uCT 760, uCT 780

Indications for Use *(Describe)*
uCT 760/780 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 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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SECTION 2

510(k) Summary

510 (k) SUMMARY

1. **Date of Preparation**
   January 19, 2018

2. **Sponsor Identification**

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

   Contact Person: Shumei Wang
   Position: QM&RA VP
   Tel: +86-021-67076888-6776
   Fax: +86-021-67076889
   Email: shumei.wang@united-imaging.com

3. **Identification of Proposed Device**

   Trade Name: uCT 760, uCT 780
   Common Name: 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

4. **Identification of Predicate Device(s)**

   Predicate Device

   510(k) Number: K033326
   Device Name: “Philips Plus” CT scanner
   Model(s): Brilliance 40, Brilliance 64

   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 760/780 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, Vital Signal Module 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 760, uCT 780.The differences between the two models are as follows:

Spec. / Model	HV Power	Rotation speed	Minimum slice thickness	Maximum slices generated per rotation
uCT 760	80kW	Up to 0.35 sec per 360° rotation	0.625mm	128
uCT 780	100kW	Up to 0.3 sec per 360° rotation	0.5mm	160

6. Indications for Use

uCT 760/780 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 and vascular).

7. Comparison of Technological Characteristics with the Predicate Devices

The uCT 760/780 Computed Tomography X-ray system has the same indications for use as the predicate device "Philips Plus" CT scanner. 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 760, uCT 780	Predicate Device Brilliance 40, Brilliance 64	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 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 and vascular).	The "Philips Plus" is a Whole Body 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.	Same
Specifications			
Scan Regime	Continuous Rotation	Continuous Rotation	Same
Scan Modes	Scout Axial Scan Helical Scan	Surview Axial Scan Helical Scan	Same
Detector Material	Solid-state GOS	Solid-state GOS	Same
Z-plane coverage	40mm	40mm	Same
Size of detector element in Z-plane	0.5mm	0.625mm	Note No.1
Number of element per row	936	672	Note No.2
Number of detector row	80	40 for Brilliance 40 64 for Brilliance 64	Note No.3
Maximum slices generated per	128 for uCT 760 160 for uCT 780	40 for Brilliance 40 64 for Brilliance 64	Note No.4

rotation (multi-slice capability)			
Minimum slice thickness	0.625mm for uCT 760 0.5mm for uCT 780	0.625mm	Same
Maximum sampling rate	Up to 4800 views per 360°	Up to 4640 views per 360°	Note No.5
Tube anode storage capacity	7.5MHU	8.0MHU	Note No.6
Maximum cooling rate	1386 kHU/min	1608kHU/min	Note No.7
Focal spot size	0.7x0.7mm 1.0x1.0mm	0.5x1.0mm 1.0x1.0mm	Note No.8
Power	80kW for uCT 760 100 kW for uCT 780	60 kW	Note No.9
mA Range	6-667mA for uCT 760 6-833mA for uCT 780	30-500mA for Brilliance 40 20-500mA for Brilliance 64	Note No.10
kV Settings	70, 80, 100, 120, 140	80, 120, 140	Note No.11
Aperture	700mm	700mm	Same
Rotation speed	Up to 0.35 sec per 360° rotation for uCT 760 Up to 0.3 sec per 360° rotation for uCT 780	Up to 0.42 sec per 360° rotation for Brilliance 40 Up to 0.4 sec per 360° rotation for Brilliance 64	Note No.12
Temporal resolution	As low as 35ms	As low as 42ms	Note No.13
Gantry Tilt	± 30°with 0.5 increment	± 30°with 0.5 increment	Same
Scannable range	1700 mm	1750mm	Note No.14
Horizontal motion range	2180 mm	1900mm	Note No.15
Table Horizontal Speed	Up to 200mm/sec	Up to 143mm/sec	Note No.16
Vertical motion range	480 mm-950 mm from the floor	578-1028mm	Note No.17
Vertical speed	Up to 40 mm/sec	Up to 50mm/sec	Note No.18
Table Horizontal Position accuracy	±0.25mm	±0.25mm	Same
Table Maximum table load	205kg	204kg	Note No.19
Image Spatial Resolution	High mode: 20 lp/cm @ MTF 0%	High mode: 16.0lp/cm 0%	Note No.20

	16.5 lp/cm @ MTF10% 11.5 lp/cm @ MTF50%	12.0 lp/cm @ MTF10% 6.0 lp/cm @ MTF50%	
Image Noise	3.0 HU at 120 kV, 5 mm slice thickness, CTDIvol 29.1mGy	4.0 HU at 120 kV, 5 mm slice thickness, CTDIvol 27.3mGy	Note No.21
CT Number Display Range	-1024 ~+8191 HU	-1024 ~+3072 HU	Note No.22
Scan Field of View	Up to 500 mm 600mm with extend FOV	Up to 500 mm	Same
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	50mm-500mm 25mm-250mm (Ultra High mode)	Note No.23
Maximum scannable length	1700mm	1750mm	Note No.24
Image Matrix	Up to 1024 x 1024	Up to 1024 x 1024	Same
Reconstructed slice thickness	uCT 760: 0.625mm,1.25mm,2.5mm,5mm,10mm (axial) 0.625-10mm(helical) uCT 780: 0.5mm,0.625mm,1.25mm,2.5mm,5mm,10mm (axial) 0.5-10mm(helical)	Spiral mode:0.67 -7.5mm Axial mode:0.5-12mm	Note No.25
Pitch	0.1~2.0	0.13~1.5	Note No.26
Maximum continuous exposure time	Up to 100seconds	Up to 100seconds	Same
Slip ring	6.25 Gbps transfer rate	Up to 5.3 Gbps transfer rate	Note No.27
RAM	24GB for console PC 32GB for Recon PC	2.0GB 4.0GB (optional)	Note No.28
Display	24inch, 1200 x 1920	19inch, 1024 x 1280	Note No.29
Safety			
Electrical Safety	Comply with ES60601-1	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
Clinical	Sample clinical image for both proposed and predicate devices are provided in Section 15 Clinical Evaluation. Electronic file for each image are provide in MISC Folder.		
Justification			

Note ID	Justification
Note 1	Provides the smaller minimum detector element size that induces higher z-plane spatial resolution for CT imaging, which does not affect safety and effectiveness.
Note 2	Provides the larger detector element number per row that induces more data sampling and higher spatial resolution per row for CT imaging, which does not affect safety and effectiveness.
Note 3	The move to 80 slices is the addition of physical detectors increasing the total number of slices to 80, which does not affect safety and effectiveness.
Note 4	With a reconstruction process and reduction in ("windmill") artifacts, 128 slices or 160 slices can be achieved from the 80 detectors. Neither of these changes affects safety and effectiveness.
Note 5	Provides the larger maximum sampling rate based on the full view (360°) that induces more data sampling and higher spatial resolution for CT imaging, which does not affect safety and effectiveness.
Note 6	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 7	Similarly with Note 7, 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 8	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 9	Provide the larger power output that induces higher ability of x-ray penetration when scanning the object with high BMI with lower possibility of photon starvation, and the safety has been evaluated by the related testing and verification.
Note 10	Provide the larger mA output that induces higher ability of x-ray penetration when scanning the object with high BMI with lower possibility of photon starvation, and the safety has been evaluated by the related testing and verification. Provide the small mA output that induces lower ability of x-ray penetration when scanning the object with low BMI with lower possibility

	of photon starvation, and the safety has been evaluated by the related testing and verification.
Note 11	Provide small kV output such as 70kV that induces lower ability of x-ray penetration when scanning the object with low BMI with lower possibility of photon starvation, and the safety has been evaluated by the related testing and verification. Provide 100KV output that induces more feasible ability of x-ray penetration when scanning the object with various BMIs, and the safety has been evaluated by the related testing and verification.
Note 12	Provides the shorter minimum scan time that induces better temporal resolution in advanced clinical applications, including cardiac imaging, which does not affect safety and effectiveness.
Note 13	Provides the shorter temporal resolution that reduces motion artifacts of cardiac imaging and increase the image quality, which does not affect safety and effectiveness.
Note 14	Scannable range between the two kinds of devices is equivalent substantially because both of them can cover all kinds of the height range of current humans and they offer helical scanner mode to scan the whole body from various human instead.
Note 15	Provide the larger horizontal motion range that induces larger scan range, which does not affect safety and effectiveness.
Note 16	Provide the larger table horizontal speed that induces shorter scan time with the other given scan conditions such as scan range and parameters, which does not affect safety and effectiveness.
Note 17	Vertical motion range is decided by device gantry and couch design which does not affect safety and effectiveness.
Note 18	Vertical speed between the two kinds of devices is equivalent substantially and 10mm/sec difference does not affect safety and effectiveness.
Note 19	The maximum table load between the two kinds of devices is equivalent substantially because both of them can cover all kinds of the load range of current humans.
Note 20	Providing the higher image spatial resolution is helpful to distinguish the smaller structure, which does not affect safety and effectiveness.
Note 21	With 120 kV and 5mm slice thickness, the image noise for typical head is 3HU on CTDIvol 29.1mGy, which is better than 4HU on CTDIvol 27.3mGy. But the image noise level is equivalent substantially considering the proposed device has measured its noise based on the larger CTDIvol than the Predicate Device.
Note 22	Provides the large HU range that induces more choice for various clinical scan situation and show more information in clinical images, which does not affect safety and effectiveness.
Note 23	Reconstruction Field of View between the two kinds of devices is equivalent substantially and the difference from lower limits does not affect safety and effectiveness.

Note 24	Maximum scannable length between the two kinds of devices is equivalent substantially because both of them can cover all kinds of the load range of current humans.
Note 25	Provides the more slice thickness that induce more choice for various clinical scan situations and thinner slice thickness should bring higher spatial resolution in z-plane, which does not affect safety and effectiveness.
Note 26	Provides the large pitch range that induces more choice for various clinical scan situations, which does not affect safety and effectiveness.
Note 27	Provides the larger data transfer rate that reduce data transfer time to increase the reconstruction performance, which does not affect safety and effectiveness.
Note 28	Provides the larger ROM that induces more store space for calculation to increase the reconstruction performance, which does not affect safety and effectiveness.
Note 29	The increase of the display size requires another best resolution, which does not affect safety and effectiveness.

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

ITEM	Proposed Device uCT 760, uCT 780	Predicate Device Brilliance 40, Brilliance 64	Remark
Application Features			
Iterative noise reduction	KARL 3D	iDOSE	Functional Equivalent
	Adaptive Filter	Adaptive Filter	Functional Equivalent
Metal artifact reduction	MAC	MAR	Functional Equivalent

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 760/780 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 760/780 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 Edition 3: 2007-03, 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 [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

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 [Including: Technical Corrigendum 1 (2006)]

Performance Verification

- Clinical Evaluation for sample clinical images evaluation;
- Artifact Evaluation Report for MAC performance study;
- Iterative Denoising Test Report for KARL performance study;
- AEC Test Report for AEC performance study.

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 760/780 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.