August 1, 2023

Shanghai United Imaging Healthcare Co., Ltd.
% Xin Gao
Regulatory Affairs Manager
No. 2258 Chengbei Rd., Jiading Industrial District
SHANGHAI 201807
CHINA

Re: K230162
Trade/Device Name: uCT 760 with uWS-CT-Dual Energy Analysis, uCT 780 with uWS-CT-Dual Energy Analysis
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: July 7, 2023
Received: July 10, 2023

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230162

Device Name
uCT 760 with uWS-CT-Dual Energy Analysis, uCT 780 with uWS-CT-Dual Energy Analysis

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).

uCT 760/780 is intended to be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.
* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

uWS-CT-Dual Energy Analysis is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The various materials of an anatomical region of interest have different attenuation coefficients, which depend on the used energy. These differences provide information on the chemical composition of the scanned body materials and enable images to be generated at multiple energies within the available spectrum. uWS-CT-Dual Energy Analysis software combines images acquired with low and high energy spectra to visualize this information.

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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510 (K) SUMMARY K230162

1. **Date of Preparation**
   July 31, 2023

2. **Sponsor Identification**

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3. **Identification of Proposed Device**

Trade Name	uCT 760 with uWS-CT-Dual Energy Analysis	uCT 780 with uWS-CT-Dual Energy Analysis
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)**

Primary Predicate Device

510(k) Number: K172135
Device Name: uCT 760, uCT 780
Regulation Name: Computed Tomography X-ray System

Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

Secondary Predicate Device 1

510(k) Number: K203448
Device Name: uCT ATLAS with uWS-CT-Dual Energy Analysis
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

Secondary Predicate Device 2

510(k) Number: K211373
Device Name: SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite SOMATOM X.ceed, Scan&GO Software
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description:

The uCT Computed Tomography X-ray system is intended to produce cross-sectional images of the patient by computer reconstruction of X-ray transmission data taken at different angles and planes. These images may be obtained either with or without contrast.

This proposed device includes two models: uCT 760 and 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

The uWS-CT-Dual Energy Analysis is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The various materials of an anatomical region of interest have different attenuation coefficients, which depend on the used energy. These differences provide information on the chemical composition of the scanned body materials. CT dual energy analysis application combines images acquired with low and high energy spectra to visualize this information.

The modification performed on the uCT 760 & 780 in this submission is mainly due to the following new features:

- Low Dose CT Lung Cancer Screening Protocol
- uAI Vision
- Auto ALARA kVp
- Organ-Based Auto ALARA mA
- CT-Guided Intervention
- Injector Linkage
- Dual Energy Analysis

CT-Guided Intervention is a medical tool for assisting a minimally invasive procedure. CT-Guided Intervention in uCT 760/780 is to provide CT-imaging guidance for interventional procedures. During the CT-Guided Intervention procedure, CT images can help the user guide the needle entry path before operating a minimally invasive procedure and display the placement of the needle during a minimally invasive procedure based on the four scan modes: Single Axial, Continuous, Fluoro and Single helical. In this case, cells or tissue can be taken for biopsy, or minimally invasive surgeries such as drainage and ablation can be performed.

Comparison details are shown in Section 7.

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).

uCT 760/780 is intended to be used for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.
* Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

uWS-CT-Dual Energy Analysis is a post-processing software package that accepts UIH CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The various materials of an anatomical region of interest have different attenuation coefficients, which depend on the used energy. These differences provide information on the chemical composition of the scanned body materials and enable images to be generated at multiple energies within the available spectrum. uWS-CT-Dual Energy Analysis software combines images acquired with low and high energy spectra to visualize this information.

7. **Comparison of Technological Characteristics with the Predicate Device**

The indications for use for the proposed device is same as that for the primary predicate device (K172135), except for the addition of the dual-energy functionality and the low dose CT lung cancer screening, which are same as in the indications for use for the secondary predicate device 1 (K203448).

A comparison between the technological characteristics of proposed and predicate devices is provided as below.

Table 1 Comparisons to Predicate Device and the Secondary Predicates

ITEM	Proposed Device	Predicate Device uCT 760, uCT 780 (K172135)	Secondary Predicate Device 1 uCT ATLAS with uWS-CT-Dual Energy Analysis （K203448）	Secondary Predicate Device 2 SOMATOM go.Now, SOMATOM go.Up, SOMATOM go.All, SOMATOM go.Top, SOMATOM go.Sim, SOMATOM go.Open Pro, SOMATOM X.cite SOMATOM X.ceed, Scan&GO Software（K211373）	Discussion of Differences
Specifications					
Gantry	Rotation speed: up to 0.35s/rotation for uCT 760; 0.3s/rotation for uCT 780 70cm bore	Rotation speed up to 0.35s/rotation for uCT 760; 0.3s/rotation for uCT 780 70cm bore	--	--	Same
Detector	40mm Detector Material: Solid-state GOS 80 rows, 936 channels/row Size of detector element in Z-plane: 0.5mm	40mm Detector Material: Solid-state GOS 80 rows, 936 channels/row Size of detector element in Z-plane: 0.5mm	--	--	Same
X-ray Tube	70, 80, 100, 120, 140 kV mA range: 10mA-667mA for uCT 760;10 mA-667mA, 10mA-833mA(option) for uCT 780 Anode heat capacity: 7.5MHU	70, 80, 100, 120, 140 kV mA range: 10mA-667mA for uCT 760;10 mA-667mA, 10mA-833mA(option) for uCT 780 Anode heat capacity: 7.5MHU	--	--	Same

	Maximum anode heat dissipation: 1386kHU/min Focal spot size: 0.7mm × 0.7mm 1.0mm × 1.0mm	Maximum anode heat dissipation: 1386kHU/min Focal spot size: 0.7mm × 0.7mm 1.0mm × 1.0mm			
High Voltage Generator	80kW for uCT 760; 80kW, 100kW(option) for uCT 780 70, 80, 100, 120, 140 kV	80kW for uCT 760; 80kW, 100kW(option) for uCT 780 70, 80, 100, 120, 140 kV	--	--	Same
Patient Table	Max load capacity 205kg(Standard Configuration); 318kg(High Configuration)	Max load capacity 205kg	--	--	Note 1
Maximum Slices Generated per Rotation	128 for uCT 760 160 for uCT 780	128 for uCT 760 160 for uCT 780	--	--	Same
Reconstruction Field of View	40-500mm 40-600mm with extended FOV	40-500mm 40-600mm with extended FOV	--	--	Same
Functions					
KARL 3D	Yes	Yes	--	--	Same
Metal Artifact Correction (MAC)	Yes	Yes	--	--	Same
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	40mm-500mm 40mm-600mm with extend FOV	--	--	Same
Auto ALARA mA	Yes	Yes	--	--	Same
CardioXphase	Yes	--	Yes	--	Same

Deep Recon (DELTA)	Yes	Yes	--	--	Same
Low Dose CT Lung Cancer Screening Protocol	Yes	--	Yes	--	Same
uAI Vision-EasyPositioning-EasyISO	Yes	--	Yes	--	Same
Auto ALARA kVp	Yes	--	Yes	--	Same
Organ-Based Auto ALARA mA	Yes	--	Yes	--	Same
EasyRange	Yes	--	Yes	--	Same
Injector Linkage	Yes	--	Yes	--	Same
Remote Assistance	Yes	--	Yes	--	Same
Shuttle Perfusion	Yes	--	Yes	--	Same
Real Time 3D	Yes	--	Yes	--	Same
Online MPR	Yes	--	Yes	--	Same
CT-guided Intervention					
CT-guided Intervention	Yes	**--**	**--**	Yes	Functional Equivalent
Hardware (added due to the CT-Guided Intervention)					
Scanning Room Monitor	Yes	--	--	Yes	Functional Equivalent
Exposure Foot Pedal	Yes	--	--	Yes	Functional Equivalent
Hand Cart	Yes	--	--	Yes	Functional Equivalent
Suspension Gear	Yes	--	--	Yes	Functional Equivalent
Couch Side Controller	Yes	--	--	Yes	Functional Equivalent

Scan mode (added due to the CT-Guided Intervention)					
Single Axial Mode	Yes	--	--	i-Sequence	Functional Equivalent
Single Helical Mode	Yes	--	--	i-Spiral	Functional Equivalent
Fluoro Mode	Yes	--	--	i-Fluoro	Functional Equivalent
Continuous Mode	Yes	--	--	--	Note 2
2D & 3D Path Planning	Yes	--	--	Yes	Functional Equivalent
3D Image Guidance	Yes	--	--	Yes	Functional Equivalent
Dual Energy					
Dual Energy Scan	Yes	--	Yes	--	Same
Dual Energy Analysis					
Mono Energetic Image	Yes	--	Yes	--	Same
Mixed Enhanced Image	Yes	--	Yes	--	Same
CNR(Contrast Noise Ratio) Image	Yes	--	Yes	--	Same
Water-Iodine Base Material Pair	Yes	--	Yes	--	Same
Water-Calcium Base Material Pair	Yes	--	Yes	--	Same
Calcium-Iodine Base Material Pair	Yes	--	Yes	--	Same
Uric acid-Calcium Base Material Pair	Yes	--	Yes	--	Same
Image Registration	Yes	--	Yes	--	Same
Effective Atomic Number Images	Yes	--	Yes	--	Same

· **Component analysis of kidney stones, uric acid stones or non-uric acid stones** **Component analysis of joint gout, uric acid gout or non-uric acid gout**					
Electron Density Image	Yes	--	Yes	--	Same
Virtual Non Contrast Images	Yes	--	Yes	--	Same

*: The new features that the proposed device compared to predicate device have been highlight in the table.
Note 1: The proposed device is configured with two types of patient table. One is same as the predicate device, another is with higher load capacity than the predicate device. The two tables being a major component of the proposed device are conforms to the safety standards such as IEC 60601-1 series and applicable to the performance standards in 21 CFR subchapter J and satisfy with the clinical applications. The difference will not raise new safety and effectiveness concerns.
Note 2: The proposed device adds a scan mode during the interventional operation. The difference will not raise new safety and effectiveness concerns.

8. Performance Data

- **Non-Clinical Testing**

Non-clinical testing including dosimetry and image performance tests were conducted for the uCT 760 and uCT 780 to verify that the proposed device met all design specifications as it is Substantially Equivalent (SE) to the predicate device.

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

- **Electrical Safety and Electromagnetic Compatibility (EMC)**

- ANSI AAMI ES60601-1:2005+A1:2012+A2:2021, Medical electric for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)].
- IEC 60601-1-2: 2014, Edition 4.0, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3: 2008+AMD1:2013+A2:2021, Edition 2.2, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 60601-2-44 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 60825-1: 2014, Edition 3.0, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-6: 2010+A1:2013+A2:2020, Edition 3.2, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- NEMA XR 25-2019, Computed Tomography Dose Check
- NEMA XR 28-2018, 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 61223-3-5:2004+COR1:2006, Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment

- **Software**

- NEMA PS 3.1-3.20(2016): Digital Imaging and Communications in Medicine

(DICOM)

- 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: 2009, Edition 3.0, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
  - ISO 10993-10: 2010, Edition 3.0, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

- **Other Standards and Guidances**
  - ISO 14971: 2019, Edition 3.0, 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
  - 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

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uCT 760 and uCT 780 were 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, safety equivalence, and effectiveness as the predicate devices. The differences above between the proposed device and predicate devices 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 devices.