February 16, 2023

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

Re: K223028
Trade/Device Name: uCT ATLAS Astound 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: January 11, 2023
Received: January 17, 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)*

K223028

Device Name
uCT ATLAS Astound with uWS-CT-Dual Energy Analysis

Indications for Use *(Describe)*

uCT ATLAS Astound is a computed tomography x-ray system, which is intended to produce cross-sectional images of the whole body by computer reconstruction of x-ray transmission data taken at different angles and planes. uCT ATLAS Astound is applicable to head, whole body, cardiac, and vascular x-ray Computed Tomography.

uCT ATLAS Astound 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.

510 (K) SUMMARY

K223028

1. Date of Preparation

September 29, 2022

2. Sponsor Identification

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3. Identification of Proposed Device

Device Name: uCT ATLAS Astound with uWS-CT-Dual Energy Analysis
Common Name: Computed Tomography X-ray System
Model(s): uCT ATLAS Astound

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/Reference Device(s)

Predicate Device

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

5. Device Description:

The proposed device uCT ATLAS Astound with uWS-CT-Dual Energy Analysis includes image acquisition hardware, image acquisition, reconstruction and dual energy analysis software, and associated accessories.

The uCT ATLAS Astound is a multi-slice computed tomography scanner that features the following specification and technologies.

- 40 mm z-coverage in a single axial exposure with a 80-row 0.5 mm-slice Z-Detector
- 0.25 s rotation speed for high temporal resolution, and maximum 310 mm/s fast helical scanning capability
- 82 cm bore size, 318 kg (700 lbs) maximum table load capacity allows flexible positioning and access for all patients
- The new generation reconstruction method, Deep IR (also named AIIR), which combines the model-based iterative reconstruction and deep learning technology together, in order to reduce image noise and artifacts, while at the same time improving low contrast detectability and spatial resolution
- The uAI Vision patient positioning assistance

Built upon these technologies, the uCT ATLAS Astound is designed to use less radiation dose. Further, the fast scanning capability benefits the clinical applications, especially for cardiac imaging, dynamic whole organ imaging and fast body and vascular imaging.

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.

6. Indications for Use

uCT ATLAS Astound is a computed tomography x-ray system, which is intended to produce cross-sectional images of the whole body by computer reconstruction of x-ray transmission data taken at different angles and planes. uCT ATLAS Astound is applicable to head, whole body, cardiac, and vascular x-ray Computed Tomography.

uCT ATLAS Astound 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.

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7. Comparison of Technological Characteristics with the Predicate Device

The uCT ATLAS Astound with uWS-CT-Dual Energy Analysis has the same indications for use as the predicate device uCT ATLAS with uWS-CT-Dual Energy Analysis.

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

Table 1 Comparisons to Predicate Device

ITEM	Proposed Device	Predicate Device	Discussion
Specifications			
Gantry	Rotation speed: up to 0.25s/rotation 82cm bore	Rotation speed: up to 0.25s/rotation 82cm bore	Same
Detector	40mm Detector Material: Solid-state GOS 80 rows, 936 channels/row Size of detector element in Z-plane: 0.5mm	160mm Detector Material: Solid-state GOS 320 rows, 936 channels/row Size of detector element in Z-plane: 0.5mm	Note 1
X-ray tube	60, 70, 80, 100, 120, 140 kV mA range: 10mA-667mA, 10mA-833mA(option)	60, 70, 80, 100, 120, 140 kV mA range: 10mA-833mA	Note 2

ITEM	Proposed Device	Predicate Device	Discussion
	Anode heat capacity: 30MHU equivalently Maximum anode heat dissipation: 20kW(1696kHU/min) Focal spot size: 0.4mm × 0.7mm 0.6mm × 0.7mm 1.1mm × 1.2mm	Anode heat capacity: 30MHU equivalently Maximum anode heat dissipation: 20kW(1696kHU/min) Focal spot size: 0.4mm × 0.8mm 0.6mm × 0.8mm 1.1mm × 1.2mm	
High Voltage Generator	80kW, 100kW(option) 60, 70, 80, 100, 120, 140 kV	100kW 60, 70, 80, 100, 120, 140 kV	Note 3
Patient Table	Max load capacity 205kg (Standard Configuration); 318kg (High Configuration)	Max load capacity 318kg	Note 4
Reconstruction Field of View	40-500mm 40-600mm with extended FOV	40-500mm 40-600mm with extended FOV	Same
Maximum slices generated per rotation	160	640	Note 5
Functions			
Low Dose CT Lung Cancer Screening Protocol	Yes	Yes	Same
uAI Vision- EasyPositioning EasyISO	Yes	Yes	Same
Easy Range	Yes	Yes	Same
Injector Linkage	Yes	Yes	Same
Remote Assistance	Yes	Yes	Same

ITEM	Proposed Device	Predicate Device	Discussion
Auto ALARA kVp	Yes	Yes	Same
Auto ALARA mA	Yes	Yes	Same
Organ-Based Auto ALARA mA	Yes	Yes	Same
Deep IR (which is also named AIIR)	Yes	Yes	Same
KARL 3D	Yes	Yes	Same
CardioXphase	Yes	Yes	Note 6
CardioCapture	Yes	Yes	Note 7
Metal Artifact Correction	Yes	Yes	Same

Table 2 Dual Energy comparison to Reference Devices

Item	Proposed device	Predicate Device	Discussion
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 · 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	Yes	Yes	Same
Electron Density Image	Yes	Yes	Same

Virtual Non contrast Images	Yes	Yes	Same

Justification	
Note 1	The detector dimension of the proposed device is shorter than that of the predicate device. Detector rows of the proposed device is less than those of the predicate device. The shorter detector Z-plane coverage, the longer scanning time for CT imaging. The smaller number of rows, the less image information obtained. The difference did not raise new safety and effectiveness concerns.
Note 2	The proposed device is configured with two different ranges of mA ranges. One is same with the predicate device, one is smaller than the predicate device, based on the x-ray tube hardware. Smaller mA output that induces lower ability of x-ray penetration when scanning the object with high BMI with higher possibility of photon starvation. Focal spot size of the proposed device is smaller than that of the predicate device. Smaller size is helpful for the improvement of resolution. The differences did not raise new safety and effectiveness concerns.
Note 3	The proposed device is configured with two kinds of Maximum Output Power. One is same with the predicate device, one is smaller than the predicate device. Smaller power, lower mA or kV level in X-ray. The differences did not raise new safety and effectiveness concerns.
Note 4	The proposed device is configured with two kinds of patient table. One is same with the predicate device, one is with lower load capacity than the predicate device. The two tables being a major component of the proposed device conform to the safety standards such as IEC 60601-1 series and satisfy the clinical use. The difference did not raise new safety and effectiveness concerns.
Note 5	Maximum slices generated per rotation of the proposed device is less than those of the predicate device. The less slices, the longer scanning time for CT imaging. The difference did not raise new safety and effectiveness concerns.
Note 6	The predicate device can use this function both on axial scan mode and helical scan mode. The proposed device only can use this function on helical scan mode. The difference did not raise new safety and effectiveness concerns.

Note 7	The predicate device can use this function both on axial scan mode and helical scan mode. The proposed device only can use this function on helical scan mode. The difference did not raise new safety and effectiveness concerns.

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 ATLAS Astound with uWS-CT Dual Energy Analysis 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 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 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)]

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 Guidance

- 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
- Laser Product - Conformance with IEC 60825-1; Guidance for Industry and FDA Staff (Laser Notice No. 56)

Software Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as 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 Image Evaluation

The clinical image evaluation was performed under the proposed device. Sample image of head, neck, chest, abdomen, spine, hip, knee, pelvis and so on were provided with a board certified radiologist to evaluate the image quality in this submission. Each image was reviewed with a statement indicating that image quality are sufficient for clinical diagnosis.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the uCT ATLAS Astound with uWS-CT Dual Energy Analysis 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, safety equivalence, and effectiveness 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.