November 29, 2023

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

Re: K231482
Trade/Device Name: uCT ATLAS Astound with uWS-CT-Dual Energy Analysis,
uCT ATLAS 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: November 1, 2023
Received: November 1, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Radiologic 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)*
K231482

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

Indications for Use *(Describe)*
uuCT 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.

uCT ATLAS 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 is applicable to head, whole body, cardiac, and vascular x-ray Computed Tomography.
uCT ATLAS has the capability to image a whole organ in a single rotation. Organs include, but not limited to head, heart, liver, kidney, pancreas, joints, etc.
uCT ATLAS 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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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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K231482**

# 510(k) SUMMARY

1. **Date of Preparation**
   November 1, 2023

2. **Sponsor Identification**
   **Shanghai United Imaging Healthcare Co.,Ltd.**
   No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China
   Contact Person: Xin GAO
   Position: Regulatory Affairs Manager
   Tel: +86-021-67076888-5386
   Fax: +86-021-67076889
   Email: xin.gao@united-imaging.com

3. **Identification of Subject Device**
   **Device Name:** uCT ATLAS Astound with uWS-CT-Dual Energy Analysis, uCT ATLAS with uWS-CT-Dual Energy Analysis
   **Common Name:** Computed Tomography X-ray System
   **Model(s):** uCT ATLAS Astound; uCT ATLAS
   **Regulation Name:** Computed Tomography X-ray System
   **Regulation Number:** 21 CFR 892.1750
   **Regulatory Class:** II
   **Product Code:** JAK
   **Review Panel:** Radiology

4. **Identification of Predicate/Reference Device(s)**
   **Predicate Device(s)**
   **Device Name:** uCT ATLAS Astound with uWS-CT-Dual Energy Analysis
   **510(k) Number:** K223028
   **Regulation Name:** Computed Tomography X-ray System
   **Regulation Number:** 21 CFR 892.1750
   **Regulatory Class:** II
   **Product Code:** JAK
   **Review Panel:** Radiology

**Device Name:** uCT ATLAS with uWS-CT-Dual Energy Analysis
**510(k) Number:** K203448
**Regulation Name:** Computed Tomography X-ray System
**Regulation Number:** 21 CFR 892.1750
**Regulatory Class:** II
**Product Code:** JAK
**Review Panel:** Radiology

**Reference device(s):**
**Device Name:** uCT 760, uCT780
**510(k) Number:** K230162
**Regulation Name:** Computed Tomography X-ray System
**Regulation Number:** 21 CFR 892.1750
**Regulatory Class:** II
**Product Code:** JAK
**Review Panel:** Radiology

## 5. Device Description:

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

The proposed CT system 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 computer system delivered with the CT scanner is able to run post processing applications optionally.

The Computed Tomography System family scanners referenced in this submission are comparable in indications for use, and are substantially equivalent in design, material, functionality, technology, energy source and are substantially equivalent to the predicate devices. The reason for this submission is to support the following additional function:

CT intervention provides real-time CT fluoroscopy at 12 IPS with in-room view and in-room X-ray control. It allows the user to adjust the scan parameters during operation, and scan modes can be switched according to technician's operation requirements. Entry path planning based on 2D and 3D images.

The CT guided intervention will be applicable for the UIH qualified CT systems. This indication will also be applicable for future qualified UIH CT systems.

## 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.

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

There is no change between the proposed device and the predicate device except CT-Guided Intervention function. Below is the comparison table between the proposed device, predicate device, and the reference device related to CT Guided Intervention function and the Hardware modifications due to the CT Guided Intervention:

| **Software functions** | **Subject devices** | **Predicate devices (K223028 and K203448)** | **Reference device #1 (K230162)** | **Discussion** |
|---|---|---|---|---|
| Single Axial Scan | Yes | -- | Yes | Same |
| Single Helical Scan | Yes | -- | Yes | Same |
| Fluoro Mode | Yes | -- | Yes | Same |
| Continuous Mode | Yes | -- | Yes | Same |
| 2D & 3D path planning | Yes | -- | Yes | Same |
| 3D image Guidance | Yes | -- | Yes | Same |
| **Hardware addition** | **Subject devices** | **Predicate devices (K223028 and K203448)** | **Reference device #1 (K230162)** | **Discussion** |
| Scanning room monitor | Yes | -- | Yes | Same |
| Exposure Foot Pedal | Yes | -- | Yes | Same |
| Hand Cart | Yes | -- | Yes | Same |
| Suspension Gear | Yes | -- | Yes | Same |
| Couch Side Controller | Yes | -- | Yes | Same |

## 8. Performance Data

### 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 and uCT ATLAS 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)].
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
- 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 61223-3-5:2019 Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance and constancy 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 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

In this submission, following reports related to image quality metrics and CT Guided Intervention function are renewed and submitted:

- Biocompatibility Report
- IEC 61223-3-5 Test Report
- Performance Evaluation for CT Guided Intervention

**Summary**

The features described in this premarket submission are supported with the results of the testing mentioned above, the proposed device 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. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.