May 16, 2025

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

Re: K243617
Trade/Device Name: uCT ATLAS Astound with uWS-CT-Dual Energy Analysis; uCT ATLAS with uWS-CT-Dual Energy Analysis
Regulation Number: 21 CFR 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 17, 2025
Received: April 17, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243617

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

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.
* 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

1. **Date of Preparation**
   May 14, 2025

2. **Sponsor Identification**

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   Contact Person: Xin GAO
   Position: Regulatory Affair Manager
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3. **Identification of Subject Device**

   Device Name: uCT ATLAS Astound with uWS-CT-Dual Energy Analysis
   Common Name: Computed Tomography X-ray System
   Model(s): uCT ATLAS Astound
   Regulation Name: Computed Tomography X-ray System
   Regulatory Class: II
   Product Code: JAK
   Review Panel: Radiology

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

   Device Name: uCT ATLAS Astound with uWS-CT-Dual Energy Analysis
   510(k) Number: K231482
   Regulation Name: Computed Tomography X-ray System
   Regulatory Class: II
   Product Code: JAK
   Review Panel: Radiology

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Device Name: uCT ATLAS with uWS-CT-Dual Energy Analysis
510(k) Number: K231482
Regulation Name: Computed Tomography X-ray System
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
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

5. Device Description:

The uCT ATLAS Astound with uWS-CT Dual Energy Analysis and uCT ATLAS with uWS-CT Dual Energy Analysis includes the same intended use and same indications for use as their recent cleared versions (K231482). The reason for this submission is to support the following additional functions:

- CardioXphase (optimized)
- CardioBoost
- CardioCapture (optimized)
- AIIR
- Motion Freeze
- Ultra EFOV

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

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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 table below provides the comparisons among the subject devices and the predicate/reference devices:

Software functions	Subject devices	Predicate device (K231482)	Reference device #1 (K230162)	Discussion
CardioBoost	Yes It is an image reconstruction method for cardiac scanning based on deep learning technology.	--	DELTA	Substantial Equivalent Note 1
AIIR	Yes It is an image reconstruction method that combines a modal-based iterative reconstruction and deep learning technology.	Yes	--	Substantial Equivalent Note 2
CardioXphase	Yes It can recommend the optimal phase for cardiac reconstruction, which is based on deep learning technology.	Yes	--	Substantial Equivalent Note 3
Motion Freeze	Yes It is an intelligent function based on deep learning to reduce the artifacts caused by head motion.	--	--	Substantial Equivalent Note 4
Ultra EFOV	Yes It can extend reconstruction FOV to bore size using deep learning technique.	EFOV	EFOV	Substantial Equivalent Note 5
CardioCapture	Yes It is a motion correction function for cardiac scanning to reduce coronary motion artifact, which is based on deep learning technology. Only uCT ATLAS Optimize this function	Yes Both uCT ATLAS and uCT ATLAS Astound have this function	--	Substantial Equivalent Note 6

Justification	
Note ID	Justification
Note 1	Compared to the reference device (K230162), CardioBoost in subject devices is an image reconstruction method for cardiac. The difference in the subject devices is datasets augmentation and deep learning network optimization in order to improve the overall performance for cardiac images reconstruction From the user perspective, the workflow remains the same between the subject device and reference device.

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Note 2	For uCT ATLAS: Compared to the predicate device (K231482), the differences in the subject device are datasets augmentation and deep learning network optimization to enable reconstruction for head. For uCT ATLAS Astound: Compared to the predicate device (K231482), the difference in the subject device is deep learning network optimization to improve the overall performance. From the user perspective, the workflow remains the same between the subject devices and predicate devices.
Note 3	Compared to the predicate devices (K231482), the difference in the subject device is the introduction of a new deep learning based coronaries detection algorithm to improve the performance of CardioXphase. The functionality to select the best phase flowchart already exists in the predicate devices CardioXphase (K231482). From the user perspective, the workflow remains the same between the subject devices and reference devices
Note 4	The function of Motion Freeze is an image reconstruction algorithm which intend to correct the patient head motion, this will not raise new safety and effectiveness concerns.
Note 5	Compared to the predicate devices (K231482), the difference in the subject devices is that Ultra EFOV introduces a deep learning network to improve HU accuracy in the area of extended FOV. From the user perspective, the workflow remains the same between the subject devices and reference devices.
Note 6	CardioCapture in this submission is only optimized for uCT ATLAS. Compared to the predicate device(K231482), the difference in the subject device is the introduction of the deep learning module. From the user perspective, the workflow remains the same between the subject device and predicate device. .

The difference in technological characteristics do not raise safety and effectiveness concerns. The bench test and reader evaluation were conducted, The results show that the subject devices are substantial equivalent to the predicate devices and reference devices.

Performance Data

The following performance data were provided in support of the substantial equivalence determination

Non-Clinical Testing

Non-clinical testing including bench test and reader study 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 same standards and guidance cleared in K231482.

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Software functions	Bench test
CardioBoost	The bench test for CardioBoost was performed to evaluate the subject devices IQ with CardioBoost. IQ evaluation includes: • General IQ Performance testing of metrics identified in IEC 61223-3-5 to study overall performance in a standardized and referenceable manner. General IQ tests include CT HU number test and thickness section test. • A low contrast detectability (LCD) test was performed under the guidance of CTIQ White Paper to evaluate the LCD enhancement, dose reduction and noise reduction. • A high contrast spatial resolution test was performed under the guidance of AAPM's report . The test result shows that: • CardioBoost passed the basic general IQ test which satisfied the requirement of IEC 61223-3-5. • CardioBoost showed better LCD comparing with FBP at same scanning dose and can reduce scanning dose comparing with FBP at same LCD. • CardioBoost showed better noise comparing with FBP. • CardioBoost showed better spatial resolution comparing with FBP at same scanning dose.
AIIR	The bench test for AIIR was performed to evaluate the subject devices IQ with AIIR. IQ evaluation includes: • General IQ Performance testing of metrics identified in IEC 61223-3-5 to study overall performance in a standardized and referenceable manner. General IQ tests include CT HU number test and thickness section test. • A low contrast detectability (LCD) test was performed under the guidance of CTIQ White Paper to evaluate the LCD enhancement, dose reduction and noise reduction. • A high contrast spatial resolution test was performed under the guidance of AAPM's report. The test results show that: • AIIR passed the basic general IQ test which satisfied the requirement of IEC 61223-3-5. • AIIR showed better LCD comparing with FBP at same scanning dose and can reduce scanning dose comparing with FBP at same LCD.

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	• AIIR showed better noise comparing with FBP. • AIIR showed better spatial resolution comparing with FBP at same scanning dose.
CardioXphase	The bench test for CardioXphase was performed to evaluate the extraction accuracy of new AI module in heart and coronary artery structure. Other modules are same as the function cleared in K231482. The quantitative assessment metrics for the heart mask and coronary artery mask extracted by the new AI module and the annotated results are calculated: Dice Similarity Coefficient (DICE), Precision, and Recall. The test results show that all indicators have met the verification criteria and have passed the verification.
Motion Freeze	The bench test for Motion Freeze was performed to evaluate the effectiveness on reducing head motion artifacts, by comparing the artifacts on images with- and without- Motion Freeze, The test results show that Motion Freeze can reduce head motion artifacts.
Ultra EFOV	The bench test for Ultra EFOV was performed to evaluate the effectiveness on improving CT value accuracy, by comparing the CT value of images with EFOV and the CT value of images with Ultra EFOV. The test results show that Ultra EFOV can improve the CT number, in cases where the scanned object exceeds the CT field of scan-FOV.

Software functions	**Reader study**
CardioBoost	The clinical images reconstructed with CardioBoost and KARL 3D respectively were shown to the readers to perform a five-point scale evaluation of both image sets on the several image quality aspects, including noise level, structure fidelity, image quality and clinical features. The results confirmed that CardioBoost images are sufficient for diagnosis and the image quality of CardioBoost is equal or better than the image quality of KARL 3D over all of the evaluation aspects.
AIIR	The clinical images reconstructed with AIIR and FBP respectively were shown to the readers to perform a five-point scale evaluation of both image sets on the several image quality aspects, including noise level, streaking artifact reduction and image structure fidelity. The results confirmed that AIIR images are sufficient for diagnose and the image quality of AIIR is equal or better than the image quality of FBP over all of the evaluation aspects.

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Motion Freeze	The clinical images reconstructed with Motion Freeze were shown to the readers to perform a 5-point scale evaluation of both image sets on the image quality aspects, including artifact correction effect and clinical diagnostic benefit of the images. The results confirmed that Motion Freeze is helpful for both artifact suppression and clinical diagnosis.
Ultra EFOV	The clinical images with Ultra EFOV and EFOV respectively were shown to the readers to perform a 5-point scale evaluation of both image sets on the image quality aspects, including image artifacts and homogeneity of same tissue. The results confirm that the images with Ultra EFOV can improve the accuracy of image CT numbers, in cases where the scanned object exceeds the CT field of view.
CardioCapture	AI motion correction is a new module integrated as a part of CardioCapture in uCT ATLAS. Other modules are same as the function cleared in K231482. The reader evaluation is based on the CardioCapture function with AIMC enabled. The evaluation aspects include: • Contours are clear and continuous • Motion artifacts of coronary arteries are tolerable • Number of diagnostic coronaries reaches at least 50% of the total number of coronary artery segments The results conclude the effectiveness of CardioCapture function for reducing cardiac motion artifacts as expected.

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions

Based on the comparison and analysis above, the proposed device has the 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.