January 14, 2025

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

Re: K241166
Trade/Device Name: uCT 550
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 20, 2024
Received: December 20, 2024

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 Radiologic Imaging
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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.

Submission Number *(if known)*

K241166

Device Name

uCT 550

Indications for Use *(Describe)*

The uCT 550 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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510 (K) SUMMARY

1. Date of Preparation

January 15, 2025

2. Sponsor Identification

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3. Identification of Proposed Device

Trade Name: uCT 550

Model(s): uCT 550

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

Predicate Device

Device Name: uCT 530, uCT 550

510(k) Number: K200016

Regulation Name: Computed Tomography X-ray System

Regulation Number: 21 CFR 892.1750

Regulatory Class: II

Product Code: JAK

Review Panel: Radiology

Reference device:

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

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 Computed Tomography X-ray system, uCT 550, 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. The proposed device consists of CT scan gantry (including high voltage generator, X-ray tube, collimator and detectors), patient table, operating console (including console PC, monitor and Control Box), power supply cabinet (PSC), vital signal monitoring gated control unit (VSM), 3D camera, system software, and accessories.

Compared with K200016, the proposed device was added more application features which were discussed in Chapter 7.

6. Indications for Use

The uCT 550 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 Device

Tables below provide comparisons of the technological characteristics between the proposed device, predicate device and the reference device:

ITEM	Proposed Device uCT 550	Predicate Device (K200016) uCT 530, uCT 550	Reference Device #1 (K230162) uCT 760 with uWS-CT-Dual Energy Analysis, uCT 780 with uWS-CT-Dual Energy Analysis	Discussion of Differences
Gantry	● Rotation speed: up to 0.5s/rotation; ● 70cm bore	● Rotation speed: up to 0.5s/rotation; ● 70cm bore	--	Same
Detector	● 22mm Detector ● Material: Solid-state GOS ● 40 rows, ● 864 channels/row ● Size of detector element in Z-plane: 0.55mm	● 22mm Detector ● Material: Solid-state GOS ● 40 rows, ● 864 channels/row ● Size of detector element in Z-plane: 0.55mm	--	Same

X-ray Tube	● 70, 80, 100, 120, 140 kV ● mA range: 10 mA-420 mA ● Anode heat capacity: 5.3MHU ● Maximum anode heat dissipation: 9.6kW(815kHU/min) ● Focal spot size: 0.5mm ×1.0mm 1.0mm ×1.0mm	● 70, 80, 100, 120, 140 kV ● mA range: 10 mA-420 mA ● Anode heat capacity: 5.3MHU ● Maximum anode heat dissipation: 9.6kW(815kHU/min) ● Focal spot size: 0.5mm ×1.0mm 1.0mm ×1.0mm	--	Same
High Voltage Generator	● 50kW Power ● 70, 80, 100, 120, 140 kV	● 50kW Power ● 70, 80, 100, 120, 140 kV	--	Same
Patient Table	● Maximum load capacity 205kg	● Maximum load capacity 205kg	--	Same
Maximum Slices Generated per Rotation	80 for uCT 550	40 for uCT 530 80 for uCT 550	--	Same
Reconstruction Field of View	40-500mm 40-700mm with extended FOV	40-500mm 40-600mm with extended FOV	--	Substantially Equivalent, The difference will not raise safety and effectiveness concerns.
Application Features				
KARL 3D	Yes	Yes	--	Same

Metal Artifact Correction (MAC)	Yes	Yes	--	Same
Auto ALARA mA	Yes	--	Yes	Same
Auto ALARA kVp	Yes	--	Yes	Same
Organ-Based Auto ALARA mA	Yes	--	Yes	Same
DELTA (Deep Recon)	Yes It is an AI-based deep learning algorithm to effectively reduce image noise, enhance high-contrast spatial resolution, improve low-contrast detectability, and correspondingly decrease the dose required for diagnostic CT images.	--	Yes	Substantial Equivalent Note 1
CardioXphase	Yes	--	Yes	Same
Online MPR	Yes	--	Yes	Same
EasyRange	Yes It is an AI-based deep learning algorithm to automatically recommend the scan range.	--	Yes	Substantial Equivalent Note 2
uAI Vision	Yes	--	Yes	Same
Motion Freeze	Yes	--	--	Substantial Equivalent Note 3

	It is an AI-based deep learning algorithm to reduce the artifacts caused by head motion.			
Injector Linkage	Yes	--	Yes	Same
CT-guided Intervention	Yes	--	Yes	Same
Low Dose CT Lung Cancer Screening Protocol (LDCTLCS)	Yes	--	Yes	Same
Remote Assistance	Yes	--	Yes	Same

- **Note 1:**

Compared with DELTA (Deep Recon) algorithm cleared by K230162, detailed discussion about the difference are as follows:

	Proposed device uCT 550	**Reference device uCT 760/780 with uWS-CT-Dual Energy Analysis (K230162)**	**Discussion**
Technology	AI-based deep learning algorithm	AI-based deep learning algorithm	Same
Applicable Body Parts	Head, chest, abdomen and vascular CT applications for adults	Head, chest, abdomen, cardiac and vascular CT applications for adults	The proposed device does not support cardiac. This difference will not introduce safety and effectiveness issues.
User Interface	5 noise reduction levels	4 noise reduction levels	Increased noise reduction. This difference will not introduce safety and effectiveness issues.

Dataset Size	The dataset was increased to 127 cases compared with the original dataset.	Original Dataset	Dataset was increased to improve algorithm robustness. This difference will not introduce safety and effectiveness issues.
Clinical workflow	Select recon type, strength (noise index level)	Select recon type and strength (noise index level)	Same
Bench test	Bench test for dose reduction, LCD, noise reduction and spatial resolution improving test. Basic IQ performance test including HU value on water phantom, thickness section test.	Bench test for dose reduction, LCD, noise reduction and spatial resolution improving test. Basic IQ performance test including HU value on water phantom, thickness section test.	Same
Conclusion	DELTA supplies diagnostic image quality at lower dose in the low dose simulation validation and equivalent or better image quality compared with FBP in the evaluation of clinical cases covering a variety of dose level.	DELTA is able to generate CT images with lower image noise and improved low contrast detectability, also reduce the dose required for diagnostic CT imaging.	Substantially Equivalent The function of DELTA has been optimized in the uCT 550. The difference will not raise new safety and effectiveness concerns.

- **Note 2:**

  EasyRange was optimized in this submission, adding supported body parts. The difference will not raise new safety and effectiveness concerns.

- **Note 3:**

  Motion Freeze is an image reconstruction algorithm which is intended to correct patient head motion. The difference will not raise new safety and effectiveness concerns.

8. Performance Data

The performance testing for DELTA (Deep Recon) algorithm was based on Bench Testing and the Clinical Evaluation.

8.1 Bench Testing

The bench testing has been performed to quantitatively evaluate the image quality with DELTA compared to FBP. The proposed device image quality (IQ) with DELTA was tested by the following evaluation methods.

8.1.1 Bench Test

The bench test includes different phantom tests, all phantom tests were based on 512*512 matrix sizes:

- 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 based on water phantom and Catphan 700 phantom.
- A low contrast detectability (LCD) test was performed to evaluate the LCD enhancement, dose reduction and noise reduction on MITA CCT189 and MITA CCT191 phantom.
- A high contrast spatial resolution test was performed under the guidance of IEC 61223-3-5 to evaluate the improvement of high contrast spatial resolution compared with FBP.

8.1.2 Study pass criteria

- DELTA should pass the General IQ test according to IEC 61223-3-5.
- Compared with FBP, DELTA should have better LCD and noise under same scanning dose, and DELTA can reduce scanning dose keep similar LCD compared with FBP.
- Compared with FBP, DELTA should have better high contrast spatial resolution.

8.1.3 Bench Testing Results and conclusion

- DELTA passed the basic general IQ test which satisfied the requirement of IEC 61223-3-5.
- DELTA showed better LCD and noise compared with FBP at same scanning dose and can reduce scanning dose compared with FBP at same LCD.

- DELTA showed better spatial resolution compared with FBP at same scanning dose.

In summary, the bench testing result shows that DELTA had better image noise, LCD and spatial resolution at same scanning dose compared with FBP, and DELTA can keep the image quality (LCD) under lower scanning dose compared with FBP under the above conditions/using the MITA phantom.

8.2 Clinical Evaluation

8.2.1 Clinical Evaluation Method

The proposed device was evaluated through a reader study using a sample clinical dataset. The image quality was scored by different board-certified U.S. radiologists to perform a five-point scale evaluation of both image sets on three image quality aspects: noise, image structure fidelity and overall image quality.

8.2.2 Testing Data Information

The clinical dataset comprised of different body parts, including head, chest, abdomen with disease and non-disease, gathering from different scanning doses and a wide range of population. Then, the clinical dataset was reconstructed by DELTA and FBP separately.
There were 44 datasets in total.

- The validation dataset includes 14 cases:
  -5 cases for abdomen.
  -4 cases for chest.
  -5 cases for head.

All cases were scanned at a normal dose using FBP and simulated low-dose DELTA images.

- The test dataset includes 30 cases with 10 cases for each body part—abdomen, chest, head—scanned at various doses and reconstructed using FBP and DELTA.

Validation data and Testing Data are completely independent. The distribution of validation and test data was shown below:

Body Part	Number	Age	Sex	Dose Distribution
Head	15	19-79	8 male 7 female	⩾70%: 13 30%-70%: 2 ⩽30%: 0
Chest	14	29-78	9 male 5 female	≥70%: 2 30%-70%: 4 ⩽30%: 8

Abdomen	15	29-87	9 male 6 female	≥70%: 3 30%-70% 12 ⩽30% 0

8.2.3 Clinical Acceptance Criteria

- The mean score of simulated low dose DELTA image is equal or higher than the mean score of normal dose FBP.
- The mean score of DELTA is better than the mean score of FBP under same dose.
- DELTA image should satisfy diagnosis requirements.

8.2.4 Clinical Evaluation Results and Conclusion

In general, DELTA images satisfy diagnosis requirements. All study results show that the acceptance criteria were met and that dose reductions in the clinic with DELTA should be under the supervision of a clinical medical physicist.

8.3 Declaration of Conformity

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.
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation

and testing within a risk management process

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

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 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. No issues are raised regarding the safety and effectiveness. The proposed device is determined to be Substantially Equivalent (SE) to the predicate device.