January 20, 2026

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

Re: K253173
Trade/Device Name: 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: September 26, 2025
Received: December 19, 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)*
K253173

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

Indications for Use *(Describe)*
uCT 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 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

K253173

1. Date of Preparation

December 15, 2025

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.

No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Xin GAO

Position: Regulatory Affair Manager

Tel: +86-021-67076888-5386

Fax: +86-021-67076889

Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uCT 780 with uWS-CT-Dual Energy Analysis

Common Name: Computed Tomography X-ray System

Device Name: uCT 780

Model: 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)

Predicate Device

510(k) Number: K241079

Trade Name: uCT 780 with uWS-CT-Dual Energy Analysis

Model(s): uCT 780

Regulation Number: 21 CFR 892.1750

Regulation Name: Computed Tomography X-ray System

Regulatory Class: II

Product Code: JAK

Review Panel: Radiology

5. Device Description:

The Computed Tomography X-ray system, uCT 780, 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 510(k) is to request modifications for the cleared Computed Tomography X-ray system uCT 780. uCT 780 has been previously cleared by FDA via K241079.The modification performed on the uCT 780 (K241079) in this submission is due to the addition of a new high voltage generator. At the same time, we introduce a mobile configuration which supports installation in vehicles.

A summary of the modified hardware is provided below:

- A new model of high voltage generator uXG 100 has been introduced in the mobile configuration, and the predicate model CT140N80X4889 is still used in other non-mobile configurations.
- A tilt lock has been introduced to the gantry and a horizontal movement lock has been introduced to the standard config patient table, and the system software has been updated to include the relevant controls and prompts.
- PSC has been modified, including adding a shock-absorbing base, strengthening the sheet metal structure, and optimizing the fixing method of PSC.

6. Indications for Use

uCT 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 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 differences from the predicate device are discussed in the comparison table in this submission as below.

Table 1 Comparison to Predicate Device

ITEM	**Proposed Device uCT 780 with uWS-CT-Dual Energy Analysis**	**Predicate Device uCT 780 with uWS-CT-Dual Energy Analysis (K241079)**	**Discussion of Differences**
High Voltage Generator	· Model: uXG 100 for mobile, CT140N80X4889 for non-mobile; · Maximum power: 100kW · kV settings: 70kV, 80kV, 100kV, 120kV, 140kV	· Model: CT140N80X4889 · Maximum power: 100kW · kV settings: 70kV, 80kV, 100kV, 120kV, 140kV	The proposed device adds mobile configuration and introduces a new high voltage generator (uXG 100) for mobile configuration. uXG 100 has consistent performance parameters as CT140N80X4889. The difference did not raise new safety and effectiveness concerns.
Gantry	· 40mm Detector · Rotation speed: up to 0.3s/rotation · 70cm bore	· 40mm Detector · Rotation speed: up to 0.3s/rotation · 70cm bore	Gantry tilt lock is added for mobile configuration. Performance parameters of gantry for mobile configuration is consistent as non-mobile configuration. The difference did not raise new safety and effectiveness concerns.

Patient Table	· Mobile: Standard config patient table · Non-mobile: Standard config patient table and High config patient table	· Standard config patient table · High config patient table	Only standard config patient table is used for mobile configuration. Patient table lock is added for mobile configuration. Patient table lock device does not change the performance of the standard config patient table. The difference did not raise new safety and effectiveness concerns.
VSM	· Mobile: Wireless VSM · Non-mobile: Wireless VSM and Wired VSM	· Wired VSM · Wireless VSM	Only Wireless VSM is used for mobile configuration. The difference did not raise new safety and effectiveness concerns.
PSC	• Power voltage: 380VAC/400VAC/415VAC/440VAC/460VAC/480VAC • Power frequency: 50/60 Hz	• Power voltage: 380VAC/400VAC/415VAC/440VAC/460VAC/480VAC • Power frequency: 50/60 Hz	PSC is strengthened for mobile configuration and a shock-absorbing base is added. Also, the fixing method of PSC is optimized. Performance parameters of PSC for mobile configuration are consistent as non-mobile configuration. The difference did not raise new safety and effectiveness concerns.

Based on the comparison and analysis above, the proposed device has the same intended use, similar performance, equivalence safety and effeteness in hardware and software 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 safety and effectiveness.

8. Performance Data

The following testing was conducted on uCT 780 and were provided in support of the substantial determination.

Non-Clinical Testing

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

- ✓ ANSI/AAMI ES60601-1:2005+A1:2012+A2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ✓ IEC 60601-1-2:2014+A1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ✓ 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
- ✓ IEC 60601-1-3: 2008+AMD1:2013+A2:2021, 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: 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, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- ✓ IEC 62304: 2006+AMD1:2015 CSV Consolidated version, Medical device software - Software life cycle processes

To ensure vibration, shock and environmental conditions do not impact the device performance metrics and image quality, environmental testing including pre-test, reliability test and post-test have been conducted on the proposed device. The reliability test simulates the device's exposure to vibration and shock during transportation. Pre-test and post-test are performed before and after the reliability test. Result is shown as below table.

Table 2 Result for environmental Testing

Test Item	Bench Testing Performed
Pre-test	Before reliability test, a comprehensive test is conducted on the mobile configuration of uCT 780, including device performance and image performance. The test results indicate that all test items have been passed.
Reliability Test	Vibration and shock tests are conducted on key components of the above sample device such as gantry, patient table, and

	PSC respectively according to IEC 60068-2-6, IEC 60068-2-27 and IEC 60068-2-64 . Reliability test conditions: · Sine sweep：2Hz~200Hz~2Hz as one cycle, 6 cycles in X/Y/Z direction, respectively. · Random vibration: 36h in X/Y/Z direction, respectively. · Shock: ±2.5g in X/Y direction, ±4g in Z direction; 400 cycles in each direction. During reliability condition test, the appearance of the system is in good condition, and there is no loose, damage and fracture.
Post-test	After reliability test, the system is re-integrated and the same test as Pre-test is re-conducted, including device performance and image performance. The test results indicate that all test items have been passed. The vibration and shock don't impact the device performance metrics and image quality.

The test results demonstrated that the device performed as expected and thus, it is substantial equivalent to the predicate devices to which it has been compared.

Clinical Testing

The subject of this premarket submission did not require clinical studies to support substantial equivalence.

9. Conclusions

The changes associated with mobile configuration in the uCT 780 do not create a new intended use and represent technological characteristics.
United Imaging's quality system's design verification, and risk management processes did not identify any new questions of safety or effectiveness, hazards, unexpected results, or adverse effects stemming from the changes to the predicate.
Based on development under United Imaging's quality system, the EMC testing and the Safety testing demonstrate that uCT 780 is substantially equivalent to and as safe and as effective for its intended use, as the legally marketed predicate device.