January 7, 2025

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

Re: K241079
Trade/Device Name: uCT 780
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 30, 2024
Received: December 6, 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, PhD
Assistant Director
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DHT8B: Division of Radiologic Imaging
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OHT8: Office of Radiological Health
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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)*

K241079

Device Name

uCT 780

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.

510 (K) SUMMARY

k241079

1. Date of Preparation

January 7, 2025

2. Sponsor Identification

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3. Identification of Proposed Device

Trade Name: uCT 780

Model(s): uCT 780, uWS-CT-Dual Energy Analysis

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 Device(s)

Predicate Device

510(k) Number: K230162

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

Model(s): uCT 760, uCT 780

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 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.

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.

In this submission, the DETLA (Deep Recon) feature of the proposed device is modified and there is no other significant change compared with K230162. The detail comparison of DELTA between the proposed device and the predicate device (K230162) is introduced in the below sections.

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. Substantially Equivalence Discussion

The DELTA (Deep Recon) is an AI-based reconstruction method that deployed within uCT 780 acquisition and processing software. The hardware environment and software platform for the DELTA in the proposed device and the predicate device are same. The indications for use and the scientific technology remain unchanged. The table below summarizes the Technological Characteristics between the proposed and predicate devices.

	Proposed device uCT 780 with uWS-CT-Dual Energy Analysis	**Predict device uCT 760/780 with uWS-CT-Dual Energy Analysis (K230162)**	**Discussion**
DELTA (Deep Recon)	AI-based deep learning reconstruction algorithm.	AI-based deep learning reconstruction algorithm.	Same
Applicable Body Parts	head, chest, abdomen, cardiac and vascular CT applications for adults	head, chest, abdomen, cardiac and vascular CT applications for adults	Same
User Interface	5 noise reduction levels.	4 noise reduction levels.	The user interface increased the choice for the noise reduction level. This will not introduce safety or effectiveness issues.
Dataset Size	The new dataset was increased to 127 cases compared with the original dataset.	Original Dataset	Dataset was increased .to improve robustness of the algorithm. The difference will not introduce safety or effectiveness issues.
Clinical workflow	Select recon type and strength (noise index level).	Select recon type and strength (noise index level).	Same

Phantom test	· Phantom test for dose reduction, LCD, noise and spatial resolution improving test. · Basic IQ performance test including HU value on water phantom, thickness section test. · Additional HU value test on tissue-mimicking phantom, noise spectrum power test.	· Phantom test for dose reduction, LCD, noise and spatial resolution improving test. · Basic IQ performance test including HU value on water phantom, thickness section test.	Adding more phantom tests, including HU value test on tissue-mimicking phantom and noise spectrum power test to give a more comprehensive tests results. The difference will not introduce safety and effectiveness issues.
Conclusion	DELTA is able to generate CT images at lower dose in the low dose simulation validation and generate equivalent or better image quality compared with FBP in the clinical scenarios of real scan under a variety of dose levels.	DELTA is able to generate CT images with lower image noise and improve low contrast detectability and also to reduce the dose required for diagnostic CT imaging.	Substantially Equivalent. The function of DELTA is optimized in the proposed device, which improved the algorithm framework. The difference will not introduce safety and effectiveness issues.

8. Performance Testing Information

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

8.1 Bench Test - Phantom Test

The bench testing is conducted on a variety of phantoms to quantify the improvement of images with DELTA when compared to the Standard Reconstruction Protocol using FBP. Some basic image quality tests were also performed on DELTA to confirm that it meets the diagnostic requirements. The image quality (IQ) of the proposed device was tested through the below evaluation methods:

8.1.1 Phantom Testing

- 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.
- Noise power spectrum test was applied on water phantom for more comprehensive test on DELTA.
- Mean CT value test on CT Whole Body Phantom PBU-60 phantom was applied to comparing mean HU value of different clinical relevant tissue between FBP and DELTA.
- 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 high contrast spatial resolution enhanced comparing with FBP.

8.1.2 Study pass criteria

- DELTA should pass the basic IQ test according to IEC 61223-3-5.
- Noise power spectrum of DELTA should be similar to FBP image.
- Mean CT value of DELTA under various tissues should be similar to that of FBP and the error should be less than 4HU in head and 6HU in body.
- Compared with FBP, DELTA should have better LCD and noise under same scanning dose, and DELTA can reduce scanning dose keep similar LCD comparing 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.
- Noise power spectrum of DELTA is similar to FBP.
- Mean CT value for different tissues of DELTA is less than 4HU in head and 6HU in body compared with that of FBP
- 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.

8.2 Clinical Assessment

8.2.1 Clinical Evaluation Method

The proposed device performed a reader study of sample clinical data as clinical evaluation. The image quality was scored by 2 board-certified U.S. radiologists to perform a five-point scale evaluation of both image sets on three image quality aspects: noise, structure fidelity and overall image quality.

8.2.2 Testing Data Information

The clinical datasets in the evaluation covered different head, chest, abdomen and cardiac protocol, common diseases, different scanning dose and a wide range of population. The datasets were reconstructed with DELTA and FBP.
The performance testing for DELTA algorithm was performed on 60 subjects during the product development.
The validation dataset includes 20 cases, with 5 cases for each body part—abdomen, chest, head, and cardiac—scanned at a normal dose and reconstructed using normal-dose FBP, as well as simulated low-dose DELTA images.
The test dataset includes 40 cases, with 10 cases for each body part—abdomen, chest, head, and cardiac—scanned at various doses and reconstructed using FBP and DELTA.

Validation data & Testing Data Independence

Training dataset do not contain any validation dataset or test dataset of DELTA algorithm.

The distribution of validation and test data was shown below:

Body Part	Number	Age	Sex	Dose Distribution
Head	15	27-82	6 male 9 female	≥70%: 10 30%-70%: 3 <30%: 2
Chest	15	46-81	9 male 6 female	≥70%: 3 30%-70%: 6 <30%: 6
Abdomen	15	30-87	10 male 5 female	≥70%: 5 30%-70% 5 <30% 5
Cardiac	15	29-75	7 male 8 female	≥70%: 7 30%-70% 8 <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 can have satisfy diagnosis requirement in all the evaluated image.

8.2.4 Clinical Evaluation Results and Conclusion

- Validation dataset evaluation showed that the DELTA method yielded equivalent or better image quality at lower dose compared with the FBP on them with standard dose.
- Test dataset evaluation showed that DELTA reconstruction method yielded better image quality compared with FBP reconstruction.
- All the study results show that the acceptance criteria were met.

This clinical study alone can not be used to support the promotional claim such as uCT 780 DELTA achieves equivalent or better image quality than FBP, additional tests are needed.

In summary, due to the testing limited, a consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task before using uCT 780 DELTA (Deep Recon).

uCT 780 DELTA has not been thoroughly tested in pediatric population. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task; Clinicians or dosimetrists should only be allowed to reduce patient dose in clinical practice.

In clinical practice, the use of uCT 780 DELTA may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task. Low Contrast Detectability (LCD), Image Noise were assessed using normal dose comparing uCT 780 DELTA and FBP. The LCD and Image Noise measured in 0.625mm slices. The claims are based on level 5.

9. Conclusion and Summary

The changes associated with DELTA (Deep Recon) in uCT 780 do not create a new Intended Use and represent technological characteristics that the dose is substantially reduced at the same resolution, the low contrast resolution is substantially increased at the same dose and the noise is substantially reduced.

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 successful system and software verification and validation testing, the additional engineering bench testing, and the clinical testing demonstrates that uCT 780 is substantially equivalent to and as safe and as effective for its Intended Use, as the legally marketed predicate device.