August 11, 2021

Shanghai United Imaging Healthcare Co., Ltd.
℅ Xin Gao
RA Manager
No. 2258 Chengei Rd., Jiading Industrial District
Shanghai, Shanghai 201807
CHINA

Re: K203448
Trade/Device Name: 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: July 12, 2021
Received: July 15, 2021

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K203448

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

Indications for Use *(Describe)*
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 software uses 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

K203448

1. Date of Preparation

November 18, 2020

2. Sponsor Identification

Shanghai United Imaging Healthcare Co.,Ltd.
No.2258 Chengbei Rd. Jiading District, 201807, Shanghai, China

Contact Person: Xin GAO
Position: RA Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

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

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/Reference Device(s)

Predicate Device

510(k) Number: K172135
Device Name: uCT 760, uCT 780
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Review Panel: Radiology

Reference Device #1

510(k) Number: K161009
Device Name: Aquilion ONE Vision with FIRST 2.0 (CCRS-001B) V7.4

Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK

Reference Device #2

510(k) Number: K193073
Device Name: Deep Recon
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK

Reference Device #3

510(k) Number: K132813
Device Name: DUAL ENERGY SYSTEM PACKAGE
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK

Reference Device #4

510(k) Number: K120833
Device Name: DISCOVERY CT750 HD
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK

5. Device Description:

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

The uCT ATLAS is a multi-slice computed tomography scanner that features the following specification and technologies.

- 160 mm z-coverage in a single axial exposure with a 320-row 0.5 mm-slice Z-Detector
- 0.25 s rotation speed for high temporal resolution, and maximum 440 mm/s fast volumetric scanning capability
- 82 cm bore size, 318 kg (700 lbs) maximum table load capacity allows flexible positioning and access for all patients
- The new generation reconstruction method, Deep IR (also named AIIR), which combines the model-based iterative reconstruction and deep learning technology together, in order to reduce image noise and artifacts, while at the same time

improving low contrast detectability and spatial resolution
- The uAI Vision patient positioning assistance

Built upon these technologies, the uCT ATLAS is designed to use less radiation dose than the previous generation product while maintaining the same diagnostic level of image quality. Further, the whole organ coverage and fast scanning capability benefits the clinical applications, especially for cardiac imaging, dynamic whole organ imaging and fast body and vascular imaging.

The uWS-CT-Dual Energy Analysis is a software package that uses 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.

6. Indications for Use

The proposed device uCT ATLAS with uWS-CT-Dual Energy Analysis includes a CT System and a software package.

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 software uses 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/Reference Devices

The uCT ATLAS with uWS-CT-Dual Energy Analysis has the same intended use as the predicate device uCT 760, uCT 780.

The proposed device includes more technology/features, which is discussed in the following chapters, than the predicate device. These differences will not impact the safety and effectiveness of the device.

Table 1 Comparisons to Predicate Device

ITEM	Proposed Device	Predicate Device uCT 760, uCT 780 (K172135)	Remark
Specifications			
Gantry	● 160mm Detector ● Rotation speed：up to 0.25s/rotation ● 82cm bore	● 40mm Detector ● Rotation speed：up to 0.35s/rotation (uCT 760); up to 0.3s/rotation (uCT 780) ● 70cm bore	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Patient Table	Max. load capacity 318kg	Max. load capacity 205kg	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Reconstruction Field of View	40mm-500mm 40mm-600mm with extend FOV	40mm-500mm	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Maximum slices generated per rotation	640	uCT 760:128 uCT 780:160	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Functions			
Low Dose CT Lung Cancer Screening Protocol	Yes	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
uAI Vision - EasyPositioning EasyISO	Yes,	--	Substantially Equivalent

	It's a patient positioning assistance function based on deep learning technology		The changes did not raise new safety and effectiveness concerns.
Auto ALARA kVp	Yes It can recommend the suitable kVp for the examination.	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Organ-Based Auto ALARA mA	Yes It can optimize the dose modulation for the combined chest and abdomen scan with deep learning based organ recognition.	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
CardioXphase	Yes It can recommend the optimal phase for cardiac reconstruction with less motion artifact.	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
CardioCapture	Yes It can reduce the coronary motion artifact with deep learning based coronary artery extraction.	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
EasyRange	Yes It can automatically recommend the scan range with a deep learning organ recognition technology	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Injector Linkage	Yes	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.
Remote Assistance	Yes	--	Substantially Equivalent The changes did not raise new safety and effectiveness concerns.

Table 2 Deep IR Comparison to Reference devices

Item	**Proposed device**	**Reference device #1** Aquilion ONE Vision With FIRST 2.0 (CCRS-001B) V7.4 **(K161009)**	**Reference device #2** Deep Recon **(K193073)**	**Discussion of differences**
Anatomical Region	Abdomen, pelvis, chest	Abdomen, pelvis, chest, cardiac and extremities	Abdomen, pelvis, chest, cardiac and head	Same
Exposure Dose Reduction	Yes	Yes	Yes	Same
Quantitative Dose Reduction Claim	Yes	Yes	Yes	Same
Image Quality Improvement Claim	Yes	Yes	Yes	Same
Reconstruction Technology	It is an image reconstruction method that combines a modal-based iterative reconstruction and deep learning technology.	It is an iterative reconstruction algorithm.	Dedicated deep neural network (DNN) which is trained on low dose FBP images to get normal dose (high quality) FBP images	Substantially Equivalent Testing did not raise new safety and effectiveness concerns.

Table 3 Dual Energy comparison to Reference Devices

Item	**Proposed Device**	**Reference device #3** Dual Energy System Package (K132813)	**Reference device #4** Discovery CT750 HD (K120833)	**Discussion of differences**
Dual Energy Scan	Yes	Yes	Yes	Same
Dual Energy Analysis				
Mono Energetic Image	Yes	Yes	--	Same
Mixed Enhanced Image	Yes	Yes	--	Same
CNR(Contrast Noise Ratio) Image	Yes	Yes	--	Same
Water-Iodine Base Material Pair	Yes	--	Yes	Same
Water-Calcium Base Material Pair	Yes	--	Yes	Same
Calcium-Iodine Base Material Pair	Yes	--	Yes	Same
Uric acid-Calcium Base Material Pair	Yes	--	Yes	Same
Image Registration	Yes	Yes	--	Same
Effective Atomic Number Images	Yes	--	Yes	Same
Electron Density Image	Yes	--	Yes	Same

Virtual Non contrast Images	Yes	--	Yes	Same
Component analysis of kidney stones, uric acid stones or non-uric acid stones	Yes	Yes	--	Same
Component analysis of joint gout, uric acid gout or non-uric acid gout	Yes	Yes	--	Same

8. Performance Data

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

Non-Clinical Testing

Non-clinical testing including dosimetry and image performance tests were conducted for the uCT ATLAS with uWS-CT Dual Energy Analysis during the product development.

UNITED IMAGING HEALTHCARE claims conformance to the following standards and guidance:

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety and Electromagnetic Compatibility (EMC) testing were conducted on the uCT 760/780 in accordance with the following standards:

- ES 60601-1:2005(R)2012+A1:2012+C1:2009/(R)2012+A2:2010/(R)2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- 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 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and testsIEC 60825-1 Edition 2.0 2007-03, Safety Of Laser Products - Part 1: Equipment Classification, And Requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

Product Particular Standards

- 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 60601-1-3 Edition 2.1 2013-04, Medical Electrical Equipment - Part 1-3:

General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-ray Equipment

- IEC 61223-3-5 First Edition 2004-08, Evaluation And Routine Testing In Medical Imaging Departments - Part 3-5: Acceptance Tests - Imaging Performance Of Computed Tomography X-ray Equipment [Including: Technical Corrigendum 1 (2006)]

Performance Verification

- Performance Evaluation Report for the functions
- Clinical Image Evaluation of applications

Software

- NEMA PS 3.1-3.20(2016): Digital Imaging and Communications in Medicine (DICOM)
- IEC 62304: Medical Device Software - software life cycle process
- 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 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

Other Standards and Guidances

- ISO 14971: 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
- Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; Guidance for Industry and FDA Staff (Laser Notice No. 50)
- 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

Software Verification and Validation

Software documentation for a Moderate Level of Concern software per FDA' Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" is included as a part of this submission.

The risk analysis was completed and risk control was implemented to mitigate identified hazards. The testing results show that all the software specifications have

met the acceptance criteria. Verification and validation testing of the proposed device was found acceptable to support the claim of substantial equivalence.

UNITED IMAGING HEALTHCARE conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modification, misuse or denial of use, or unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient. Cybersecurity information in accordance with guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" is included in this submission.

Clinical Testing
No Clinical Study is included in this submission.

Summary
The features described in this premarket submission are supported with the results of the testing mentioned above, the uCT ATLAS with uWS-CT Dual Energy Analysis 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, equivalence safety, and effetiveness 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.