June 24, 2019

Shanghai United Imaging Healthcare Co., Ltd.
% Xin Gao
Regulatory Affairs Specialist
NO. 2258 Chengbei Road
Shanghai, Shanghai 201807
CHINA

Re: K183170
Trade/Device Name: uWS-CT
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 28, 2019
Received: May 29, 2019

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183170

Device Name
uWS-CT

Indications for Use *(Describe)*
uWS-CT is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:
The CT Oncology application is intended to support fast-tracking routine diagnostic oncology, staging, and follow-up, by providing a tool for the user to perform the segmentation and volumetric evaluation of suspicious lesions in lung or liver.
The CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon.
The CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw.
The CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies.
The CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images.
The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels.
The CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway.
The CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in the brain.
The CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function.
The CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.
The CT Dynamic Analysis application is intended to provide visualization of the CT datasets over time with the 3D/4D display modes.
The CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk.
The CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.

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

K183170

1. **Date of Preparation:**
May 28, 2019

2. **Sponsor Identification**

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

Establishment Registration Number: 3011015597

Contact Person: Xin Gao
Position: Regulatory Affairs Specialist
Tel: +86-021-67076888-5386
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Email: xin.gao@united-imaging.com

3. **Identification of Proposed Device**

Trade Name: uWS-CT
Common Name: CT Image Post-Processing Software
Model(s): uWS-CT

Regulatory Information
Classification Name: Picture archiving and communications system
Classification: II
Product Code: LLZ
Regulation Number: 21 CFR 892.2050
Review Panel: Radiology

4. **Identification of Predicate Device(s)**

Predicate Device
510(k) Number: K173001
Device Name: uWS-CT

Reference Device#1
510(k) Number: K103480
Device Name: THORACIC VCAR

Reference device#2
510(k) Number: K033326

Device Name: "Philips Plus" CT Scanner

Reference device#3
510(k) Number: K090546
Device Name: nordicICE Software

Reference device#4
510(k) Number: K113442
Device Name: 3Di including Viewing of Mammography images

Reference device#5
510(k) Number: K150843
Device Name: syngo.via

Reference device#6
510(k) Number: K120331
Device Name: syngo.CT Dynamic Angio

Reference device#7
510(k) Number: K133643
Device Name: syngo.CT Liver Analysis

Reference device#8
510(k) Number: K162025
Device Name: IntelliSpace Portal Platform

5. Device Description

uWS-CT is a comprehensive software solution designed to process, review and analyze CT studies. It can transfer images in DICOM 3.0 format over a medical imaging network or import images from external storage devices such as CD/DVDs or flash drives. These images can be functional data, as well as anatomical datasets. It can be at one or more time-points or include one or more time-frames. Multiple display formats including MIP and volume rendering and multiple statistical analysis including mean, maximum and minimum over a user-defined region is supported. A trained, licensed physician can interpret these displayed images as well as the statistics as per standard practice.

This proposed device contains the following modifications/improvements in comparison to the predicate device uWS-CT:

1) Modified Indications for Use Statement;
2) Modified CT Lung Density Analysis, CT Heart and CT Calcium Scoring application;

3) Added some advanced applications:
   - CT Brain Perfusion
   - CT Dynamic Analysis
   - CT Bone Structure Analysis
   - CT Liver Evaluation

6. Indications for use

uWS-CT is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications:

- The CT Oncology application is intended to support fast-tracking routine diagnostic oncology, staging, and follow-up, by providing a tool for the user to perform the segmentation and volumetric evaluation of suspicious lesions in lung or liver.
- The CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon.
- The CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw.
- The CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway.
- The CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies.
- The CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images.
- The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels.
- The CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain.
- The CT Heart application is intended to segment heart and extract coronary artery. It also provides analysis of vascular stenosis, plaque and heart function.
- The CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score.
- The CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes.

- The CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk.
- The CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.

7. Summary of Technological Characteristics

uWS-CT is a medical diagnostic application for viewing, manipulation, 3D visualization, post-processing and comparison of medical images. After importing the DICOM image data into the system, the operator is able to perform image browsing and processing and can further obtain advanced information for diagnosis. This is identical to the predicate device.

The following tables compare the main features, principles of operation, fundamental scientific technology and intended use of uWS-CT when compared to the predicate devices.

8. Substantially Equivalent (SE) Comparison

Both the proposed and predicate device have the same general information, such as Device Classification Name, Product Code, Classification Panel, etc. and visualization and measurement technological features：

- Image communication
- Hardware /OS
- Patient Administration
- Review 2D
- Review 3D
- Filming
- Fusion
- Inner View
- Visibility
- ROI/VOI
- MIP Display
- Compare

The proposed and predicate device also have the same advanced applications in following:

- CT Oncology
- CT Dental Application
- CT Colon Analysis
- CT Vessel Analysis

- CT Lung Nodule

The differences between the proposed and the predicate device are about advanced applications, and are listed as follows:

- CT Lung density Analysis application has been modified, 6 new functions were added as follows. Substantial equivalence of these functions between the proposed and their corresponding reference device is discussed in Table 2.
    - Lung Contour Editing
    - Pulmonary lobes Segmentation
    - Airway Segmentation
    - Airway Tree Extraction and Editing
    - Airway Contour Editing
    - Statistical Analysis
- CT Heart and CT Calcium Scoring applications have been modified. Substantial equivalence of these applications between the proposed and their corresponding reference device is discussed in Table 2.
- The proposed device has added 4 new features to the predicate device. Substantial equivalence of these 4 features between the proposed and the corresponding reference device is also discussed in Table 2.
    - CT Brain Perfusion
    - CT Dynamic Analysis
    - CT Bone Structure Analysis
    - CT Liver Evaluation

Table 1 Comparison of general information

Item	Proposed Device uWS-CT	Predicate Device uWS-CT(K173001)	Remark
General			
Device Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications System	Same
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Device Class	II	II	Same
Classification Panel	Radiology	Radiology	Same
Advanced Application	Yes	Yes	The proposed device includes more applications, which is discussed in the following sections, than the predicate device. This difference will not impact the safety and effectiveness of the device.
Intended Use	uWS-CT is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: • The CT Oncology application is intended to support fast-tracking routine diagnostic oncology, staging, and follow-up, by providing a tool for the user to perform the segmentation and volumetric evaluation of suspicious lesions in lung or liver. • The CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon.	uWS-CT is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It supports interpretation and evaluation of examinations within healthcare institutions. It has the following additional indications: • The CT Oncology application is intended to support fast-tracking routine diagnostic oncology, staging, and follow-up, by providing the segmentation and volumetric evaluation of suspicious lesions in lung or liver.	The intended use is supplemented. The proposed device includes more applications, which is discussed in the following sections, than the predicate device. This difference will not impact the safety and effectiveness of the device.

Item	Proposed Device uWS-CT	Predicate Device uWS-CT(K173001)	Remark
	• The CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. • The CT Lung Density Analysis application is intended to segment pulmonary, lobes, and airway, providing the user quantitative parameters, structure information to evaluate the lung and airway. • The CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. • The CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. • The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels. • The CT Brain Perfusion application is intended to calculate the parameters such as: CBV, CBF, etc. in order to analyze functional blood flow information about a region of interest (ROI) in brain. • The CT Heart application is intended to segment heart and extract coronary artery .It also provides analysis of vascular stenosis, plaque and heart function. • The CT Calcium Scoring application is intended to identify calcifications and calculate the calcium score. • The CT Dynamic Analysis application is intended to support visualization of the CT datasets over time with the 3D/4D display modes. • The CT Bone Structure Analysis application is intended to provide visualization and labels for the ribs and spine, and support batch function for intervertebral disk.	• The CT Colon Analysis application is intended to provide the user a tool to enable easy visualization and efficient evaluation of CT volume data sets of the colon. • The CT Dental application is intended to provide the user a tool to reconstruct panoramic and paraxial views of jaw. • The CT Lung Density application is intended to provide the user a number of density parameters and structure information for evaluating tomogram scans of the lung. • The CT Lung Nodule application is intended to provide the user a tool for the review and analysis of thoracic CT images, providing quantitative and characterizing information about nodules in the lung in a single study, or over the time course of several thoracic studies. • The CT Vessel Analysis application is intended to provide a tool for viewing, manipulating, and evaluating CT vascular images. • The Inner view application is intended to perform a virtual camera view through hollow structures (cavities), such as vessels.	

Item	Proposed Device uWS-CT	Predicate Device uWS-CT(K173001)	Remark
	• The CT Liver Evaluation application is intended to provide processing and visualization for liver segmentation and vessel extraction.. It also provides a tool for the user to perform liver separation and residual liver segments evaluation.		

Table 2 SE Discussion for different Advanced Applications

Application	**Function name**	**Proposed device** uWS-CT	**Predicate device:** uWS-CT(K173001)	**Reference device#1** AW SERVER (K103480)	**Remark**
CT Lung density Analysis	Lung Segmentation	Yes	Yes	/	Same, no change
	Calculation of Lung Density	Yes	Yes	/	Same, no change
	Histogram Analysis	Yes	Yes	/	Same, no change
	Table Statistics	Yes	Yes	/	Same, no change
	VRT Protocol Display	Yes	Yes	/	Same, no change
	Save, Report, Print	Yes	Yes	/	Same, no change
	Lung Contour Editing	Yes	/	Yes	Same
	Pulmonary lobes Segmentation	Yes	/	Yes	Same
	Airway Segmentation	Yes	/	Yes	Same
	Airway Tree Extraction and Editing	Yes	/	Yes	Same
	Airway Contour Editing	Yes	/	Yes	Same
	Statistical Analysis	Yes	/	Yes	Same

Application	Function name	Proposed device uWS-CT	Reference device#2 "Philips Plus" CT Scanner (K033326)	Reference device#3 nordicICE Software (K090546)	Remark
CT Brain Perfusion	Motion Correction	Yes	Yes	/	Same
	Threshold based segmentation	Yes	Yes	/	Same
	Select the artery	Yes	Yes	/	Same
	Vessel Suppression	Yes	Yes	/	Same
	Calculating parameter map	Yes	/	Yes	Same
	Time-density curve analysis	Yes	Yes	/	Same
	Ischemic penumbra analysis	Yes	Yes	/	Same
	Image fusion	Yes	Yes	/	Same
	Symmetrical ROI analysis	Yes	Yes	/	Same
	Save, Report, Print	Yes	Yes	/	Same

Application	Function name	Proposed device uWS-CT	Reference device#4 3Di including Viewing of Mammography images (K113442)	Remark
CT Heart	Multi-Phase Loading	Yes	Yes	Same
	Heart Chamber Segmentation	Yes	Yes	Same
	Coronary Artery Extraction	Yes	Yes	Same
	Editing Tools	Yes	Yes	Same
	Centerline Extraction	Yes	Yes	Same
	Stenosis Analysis	Yes	Yes	Same
	Plaque Analysis	Yes	Yes	Same
	Cardiac function Assessment	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uWS-CT	Reference device#4 3Di including Viewing of Mammography images (K113442)	Remark
CT Calcium Scoring	Calcium sites segmentation	Yes	Yes	Same
	Calculate Calcium score	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uWS-CT	Predicate Device#5 syngo.via (K150843)	Remark
CT Bone Structure Analysis	Labeling Ribs	Yes	Yes	Same
	Labeling Spine	Yes	Yes	Same
	Batch	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uWS-CT	Reference device#6 syngo.CT Dynamic Angio (K120331)	Remark
CT Dynamic Analysis	Motion correction	Yes	Yes	Same
	Multiple phase viewing	Yes	Yes	Same
	Bone Removal	Yes	Yes	Same
	Dynamic CT datasets viewing in 3D/4D mode	Yes	Yes	Same
	Save, Report, Print	Yes	Yes	Same

Application	Function name	Proposed device uWS-CT	Reference device#7: syngo.CT Liver Analysis (K133643)	Reference device#8 IntelliSpace Portal Platform (K162025)	Remark
CT Liver Evaluation	Phase Selection	Yes	Yes	/	Same
	Liver Segmentation	Yes	Yes	/	Same
	Lesion Segmentation	Yes	Yes	/	Same
	Vessel Extraction	Yes	Yes	/	Same
	Vascular Editing	Yes	Yes	/	Same
	Liver Segments	Yes	/	Yes	Same
	Virtual Planning	Yes	Yes	/	Same
	RFA	Yes	/	Yes	Same
	Measurement	Yes	Yes	/	Same
	Save, Report, Print	Yes	Yes	/	Same

9. Performance Data

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

Biocompatibility
Not Applicable to the proposed device, because the device is stand-alone software.

Electrical Safety and Electromagnetic Compatibility (EMC)
Not Applicable to the proposed device, because the device is stand-alone software.

Software Verification and Validation
Software verification and validation testing was provided to demonstrate safety and efficacy of the proposed device. This includes a hazard analysis, and the potential hazards have been classified as a moderate level of concern (LOC). Those documentations include:

- Software description
- Hazard Analysis
- Software requirements specification (SRS)
- Software Architecture Description
- Software Development Environment Description
- Software Verification and Validation
- Cyber security Documents

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Verification

- Performance Evaluation Report for CT Lung Density Analysis
- Performance Evaluation Report for CT Brain Perfusion
- Performance Evaluation Report for CT Heart
- Performance Evaluation Report for CT Calcium Scoring
- Performance Evaluation Report for CT Dynamic Analysis
- Performance Evaluation Report for CT Bone Structure
- Performance Evaluation Report for CT Liver Evaluation

Other Standards and Guidance

- NEMA PS 3.1 - 3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2016).
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2007).
- IEC 62304 Medical device software - Software life cycle processes (Edition 1.1, 2015).

Summary

The features described in this premarket submission are supported with the results of the testing mentioned above; the uWS-CT was found to have a safety and effectiveness profile that is similar to the predicate device and reference devices.

10. Substantially Equivalent (SE) Conclusion

The proposed device is equivalent to the predicate device with regard to safety and efficacy. This conclusion is based upon a comparison of intended use, technological characteristics, performance specification, device hazards as well as verification and validation results.

In summary, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device and reference devices.