



November 7, 2018

Shanghai United Imaging Healthcare Co., Ltd.  
% Shumei Wang  
QM&RA VP  
No.2258 Chengbei Road, Jiading District  
Shanghai, 201807  
CHINA

Re: K173001

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: October 9, 2018  
Received: October 10, 2018

Dear Shumei Wang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "Robt Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for  
Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173001

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 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.

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

K173001

### 1. Date of Preparation:

March 26, 2018

### 2. Sponsor Identification

#### **Shanghai United Imaging Healthcare Co.,Ltd.**

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

Establishment Registration Number: Not yet registered for the Number

Contact Person: Shumei Wang

Position: QM&RA VP

Tel: +86-021-67076888-6776

Fax: +86-021-67076889

Email: shumei.wang@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:** K123920

**Device Name:** syngo.via

#### **Reference Device#1**

**510(k) Number:** K033326

**Device Name:** “Philips Plus” CT Scanner

#### **Reference device#2**

**510(k) Number:** K162025

**Device Name:** IntelliSpace Portal Platform

**Reference device#3**

**510(k) Number:** K081985

**Device Name:** AW SERVER

**Reference device#4**

**510(k) Number:** K023785

**Device Name:** Lung Nodule Assessment and Comparison Option (LNA)

## **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.

## **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 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.

## **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**

The proposed device has similar indications for use and overall function and performs in a similar manner with respect to, display, review and processing applications with predicate device and reference device.

Table 1 SE Discussion for basic functions

| Item                       | Proposed Device<br>uWS-CT                                                                                                                                              | Predicate Device<br>syngo.via(K123920)                                                                                                                                 | Remark |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| <b>General</b>             |                                                                                                                                                                        |                                                                                                                                                                        |        |
| 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   |
| <b>Specification</b>       |                                                                                                                                                                        |                                                                                                                                                                        |        |
| Image communication        | Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image.                                                               | Standard network protocols like TCP/IP and standard communication protocol DICOM. Additional fast image.                                                               | Same   |
| Hardware /OS               | Windows 7                                                                                                                                                              | Windows 7                                                                                                                                                              | Same   |
| Patient Administration     | Display and manage the image data information of all patients stored in the database.                                                                                  | Display and manage the image data information of all patients stored in the database.                                                                                  | Same   |
| Review 2D                  | 2D Review consists of basic processing of the 2D images, e.g. rotation, scaling, translation, windowing, and measurements.                                             | 2D Review consists of basic processing of the 2D images, e.g. rotation, scaling, translation, windowing, and measurements.                                             | Same   |
| Review 3D                  | 3D Review consist of functionalities for displaying and processing image in the 3D form, e.g. VR, CPR, MPR, MIP, etc. The module also includes tools for VOI analysis. | 3D Review consist of functionalities for displaying and processing image in the 3D form, e.g. VR, CPR, MPR, MIP, etc. The module also includes tools for VOI analysis. | Same   |
| Filming                    | Filming is a module dedicated for image printing. The print tools provide layout editing for both single images and series.                                            | Filming is a module dedicated for image printing. The print tools provide layout editing for both single images and series.                                            | Same   |
| Fusion                     | Including registration, Manual registration, Spot registration                                                                                                         | Including registration, Manual registration, Spot registration                                                                                                         | Same   |
| Inner View                 | Inner view the vessel , colon , trachea                                                                                                                                | Inner view the vessel , colon , trachea                                                                                                                                | Same   |

| Item        | Proposed Device<br>uWS-CT                                                                                                                                                                           | Predicate Device<br>syngo.via(K123920)                                                                                                                                                              | Remark |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Visibility  | User-defined the display property of fused image: Adjustment of preset of T/B value; Adjustment of the fused rate; Adjustment of pse                                                                | User-defined the display property of fused image: Adjustment of preset of T/B value; Adjustment of the fused rate; Adjustment of pse                                                                | Same   |
| ROI/VOI     | Plotting ROI or VOI, and obtaining the maximum activity value, the minimum activity value, mean activity value, the volume/area of region, and the maximum diameter of volume, peak activity value; | Plotting ROI or VOI, and obtaining the maximum activity value, the minimum activity value, mean activity value, the volume/area of region, and the maximum diameter of volume, peak activity value; | Same   |
| MIP Display | The image can be displayed as MIP and rotating play                                                                                                                                                 | The image can be displayed as MIP and rotating play                                                                                                                                                 | Same   |
| Compare     | Load two studies to compare.                                                                                                                                                                        | Load two studies to compare.                                                                                                                                                                        | Same   |

Table 2 SE discussion for additional applications

| Application     | Function name                 | Proposed device<br>uWS-CT | Predicate Device<br>syngo.via<br>(K123920) | Reference device#1:<br>“Philips Plus”<br>CT Scanner<br>(K033326) | Reference device#2:<br>IntelliSpace<br>Portal<br>Platform<br>(K162025) | Reference device#3:<br>AW<br>SERVER<br>(K081985) | Reference device#4:<br>Lung Nodule<br>Assessment and<br>Comparison<br>Option (LNA)<br>(K023785) | Remark |
|-----------------|-------------------------------|---------------------------|--------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------|--------|
| CT Lung density | Lung and Trachea Segmentation | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                 | Calculation of Lung Density   | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                 | Histogram Analysis            | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                 | Table Statistics              | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                 | VRT Protocol Display          | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                 | Save, Report, Print           | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |

| Application              | Function name                                | Proposed device<br>uWS-CT | Predicate Device<br>syngo.via<br>(K123920) | Reference device#1:<br>“Philips Plus”<br>CT Scanner<br>(K033326) | Reference device#2:<br>IntelliSpace<br>Portal<br>Platform<br>(K162025) | Reference device#3:<br>AW<br>SERVER<br>(K081985) | Reference device#4:<br>Lung Nodule<br>Assessment and<br>Comparison<br>Option (LNA)<br>(K023785) | Remark |
|--------------------------|----------------------------------------------|---------------------------|--------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------|--------|
| CT Oncology              | Compare display                              | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Registration                                 | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Manual registration                          | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | lung nodules<br>segmentation                 | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | liver lesions<br>segmentation                | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Spread                                       | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Statistical Analysis                         | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Save, Report, Print                          | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
| CT Dental<br>Application | Setting Reference<br>Line in 3D MIP<br>Image | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Plotting Panoramic<br>Curve                  | Yes                       | //                                         | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Marking Nerve Lines                          | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Sectional View<br>Analysis                   | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Dental VRT Display                           | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Save                                         | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Print                                        | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Report                                       | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                          | Pre-processing                               | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |

| Application        | Function name                                 | Proposed device<br>uWS-CT | Predicate Device<br>syngo.via<br>(K123920) | Reference device#1:<br>“Philips Plus”<br>CT Scanner<br>(K033326) | Reference device#2:<br>IntelliSpace<br>Portal<br>Platform<br>(K162025) | Reference device#3:<br>AW<br>SERVER<br>(K081985) | Reference device#4:<br>Lung Nodule<br>Assessment and<br>Comparison<br>Option (LNA)<br>(K023785) | Remark |
|--------------------|-----------------------------------------------|---------------------------|--------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------|--------|
| CT Colon Analysis  | Electronic Colon Cleansing                    | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Manual Polyps Labeling                        | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Polyps’ Quantitative Calculation and Analysis | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Virtual Endoscopy                             | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Multi-Views Display                           | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Colon edit                                    | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Save, Report, Print                           | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
| CT Vessel Analysis | Blood Vessel Center Lines Extraction          | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | VOI Segmentation                              | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Organizations Management                      | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Vessel Tracking                               | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Filter floaters                               | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Save, Report, Print                           | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | One click Bones Removal                       | Yes                       | /                                          | /                                                                | Yes                                                                    | /                                                | /                                                                                               | Same   |
|                    | DSA Bone Removal                              | Yes                       | Yes                                        | /                                                                | /                                                                      | /                                                | /                                                                                               | Same   |
|                    | Vascular Measurement                          | Yes                       | /                                          | /                                                                | /                                                                      | Yes                                              | /                                                                                               | Same   |

| Application    | Function name       | Proposed device<br>uWS-CT | Predicate Device<br>syngo.via<br>(K123920) | Reference device#1:<br>“Philips Plus”<br>CT Scanner<br>(K033326) | Reference device#2:<br>IntelliSpace<br>Portal<br>Platform<br>(K162025) | Reference device#3:<br>AW<br>SERVER<br>(K081985) | Reference device#4:<br>Lung Nodule<br>Assessment and<br>Comparison<br>Option (LNA)<br>(K023785) | Remark |
|----------------|---------------------|---------------------------|--------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------|--------|
| CT Lung Nodule | Mark the nodule     | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                | Compare the study   | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                | Save, Report, Print | Yes                       | /                                          | Yes                                                              | /                                                                      | /                                                | /                                                                                               | Same   |
|                | Lung Segmentation   | Yes                       | /                                          | /                                                                | /                                                                      | /                                                | Yes                                                                                             | Same   |
|                | Nodule Segmentation | Yes                       | /                                          | /                                                                | /                                                                      | /                                                | Yes                                                                                             | Same   |
|                | Measurement         | 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 Nodule
- Performance Evaluation Report For CT Oncology
- Performance Evaluation Report For CT Colonoscopy
- Performance Evaluation Report For CT Fusion
- Performance Evaluation Report For CT Inner View
- Performance Evaluation Report For CT Vessel

## **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.