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

April 5, 2018

Re: K172998
Trade/Device Name: uWS-MI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 30, 2018
Received: April 2, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

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)*
K172998

Device Name
uWS-MI

Indications for Use *(Describe)*
uWS-MI 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 PET/CT Oncology application is intended to provide tools to display and analyze the follow-up PET/CT data, with which users can do image registration, lesion segmentation, and statistical analysis.

The PET/CT Dynamic Analysis application is intended to display the dynamic PET image data and its associated time-activity curve.

The PET/CT Brain Analysis (NeuroQ^{TM}) application is intended to analyze the brain PET scan, give quantitative results of the relative activity of 240 different brain regions, and make comparison of activity of normal brain regions in AC database.

The PET/CT Cardiac Analysis (ECTb^{TM}) application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.

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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SECTION 3

510(k) Summary

510 (k) SUMMARY

1. **Date of Preparation:**
   March 29, 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 or 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-MI
   Common Name: PET/CT Image Post-Processing Software
   Model(s): uWS-MI

   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: K101749
   Device Name: Syngo™TrueD Software

   Reference Device#2
   510(k) Number: K063324
   Device Name: PET VCAR

Reference Device#3
510(k) Number: K130451
Device Name: NeuroQ™3.6

Reference Device#4
510(k) Number: K130902
Device Name: Emory Cardiac Toolbox™3.2

5. Device Description

uWS-MI is a comprehensive software solution designed to process, review and analyze PET, CT and PET/CT patient 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, such as PET as well as anatomical datasets, such as CT. 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-MI 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 PET/CT Oncology application is intended to provide tools to display and analyze the follow-up PET/CT data, with which users can do image registration, lesion segmentation, and statistical analysis.
- The PET/CT Dynamic Analysis application is intended to display the dynamic PET image data and its associated time-activity curve.
- The PET/CT Brain Analysis (NeuroQ™) application is intended to analyze the brain PET scan, give quantitative results of the relative activity of 240 different brain regions, and make comparison of activity of normal brain regions in AC database.
- The PET/CT Cardiac Analysis (ECTb™) application is intended to provide cardiac short axis reconstruction, browsing function. And it also performs perfusion analysis, activity analysis and cardiac function analysis of the cardiac short axis.

7. Summary of Technological Characteristics

uWS-MI 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-MI when compared to the predicate devices.

8. Substantially Equivalent (SE) Comparison

The proposed device has similar indications for use, provides similar overall functions and performs in a similar manner with the predicate device and reference devices.

Table 1 SE discussion for basic functions

Item	**Proposed Device** uWS-MI	**Predicate Device** syngo.via(K123920)	**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
Specification			
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	3D Review consist of functionalities for	Same

Item	Proposed Device uWS-MI	Predicate Device syngo.via(K123920)	Remark
	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.	displaying and processing image in the 3D form, e.g. VR, CPR, MPR, MIP, etc. The module also includes tools for VOI analysis.	
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 Auto registration, Manual registration, Spot registration	Including Auto registration, Manual registration, Spot registration	Same
Inner View	Inner view the vessel , colon , trachea	Inner view the vessel , colon , trachea	Same
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 advanced applications

Application	**Function name**	**Proposed device** uWS-MI	**Reference device#1:** Syngo^{TM}TrueD Software (K101749)	**Reference device#2:** GE PET VCAR (K063324)	**Reference device#3:** Neuroq^{TM}3.6 (K130451)	**Reference device#4:** Syntermed Emory Cardiac ToolboxTM3.2 (K130902)	**Remark**
PET/CT Dynamic Analysis	Reframe/Rebin	Yes	Do not have the function of data reframe	/	/	/	The Reframe/Rebin module is applied to generate combined data of any time phase defined by the user. This difference will not impact the safety and effectiveness of the device.
	ROI Analysis	Yes	Yes	/	/		Same
	Pseudo color	Yes	Yes	/	/		Same
	Automatic cine	Yes	Yes	/	/		Same
	Curve Analysis	Yes	Yes	/	/		Same
	Table Statistics	Yes	Yes	/	/		Same
	Save	Yes	Yes	/	/		Same
	Filming	Yes	Yes	/	/		Same
PET/CT Oncology	Compare display	Yes	/	Yes	/	/	Same
	Auto registration	Yes	/	Yes	/	/	Same

Application	Function name	Proposed device uWS-MI	Reference device#1: Syngo™TrueD Software (K101749)	Reference device#2: GE PET VCAR (K063324)	Reference device#3: Neuroq™3.6 (K130451)	Reference device#4: Syntermed Emory Cardiac ToolboxTM3.2 (K130902)	Remark
	Manual registration	Yes	/	Yes	/	/	Same
	Fix Segmentation	Yes	/	Yes	/	/	Same
	Adaptive Segmentation	Yes	/	Yes	/	/	Same
	Spread	Yes	/	Yes	/	/	Same
	Statistical Analysis	Yes	/	Yes	/	/	Same
	Save	Yes	/	Yes	/	/	Same
PET/CT Brain Analysis (Neuroq™3.6)	Reformat	Yes	/	/	Yes	/	Same
	Quality Control	Yes	/	/	Yes	/	Same
	Slice Display	Yes	/	/	Yes	/	Same
	Compare	Yes	/	/	Yes	/	Same
	PET/CT Fusion	Yes	/	/	Yes	/	Same
	EQuAL analysis	Yes	/	/	Yes	/	Same
	AmyQ	Yes	/	/	Yes	/	Same
	Save results, Capture region/display , Exit	Yes	/	/	Yes	/	Same
PET/CT	Reconstruction	Yes	/	/	/	Yes	Same

Application	**Function name**	**Proposed device** uWS-MI	**Reference device#1:** Syngo™TrueD Software (K101749)	**Reference device#2:** GE PET VCAR (K063324)	**Reference device#3:** Neuroq™3.6 (K130451)	**Reference device#4:** Syntermed Emory Cardiac ToolboxTM3.2 (K130902)	**Remark**
Cardiac Analysis (Emory Cardiac Toolbox™3.2)	SSS	Yes	/	/	/	Yes	Same
	Polor Maps	Yes	/	/	/	Yes	Same
	Perfusion Analysis	Yes	/	/	/	Yes	Same
	Viability Analysis	Yes	/	/	/	Yes	Same
	Functional Analysis	Yes	/	/	/	Yes	Same
	Save results, Capture region/display , Exit	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). These 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 PET/CT Oncology and Image Fusion
- The PET/CT Brain Analysis (NeuroQ^{TM}) application was cleared by FDA under K130451 on May 17th 2013
- The PET/CT Cardiac Analysis (ECTb^{TM}) application was cleared by FDA under K130902 on June 14th 2013.

Product 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-MI was found to have a safety and effectiveness profile that is similar to the predicate device.

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.