Shanghai United Imaging Healthcare Co., Ltd.   June 11, 2020
 Jiading District
℅ Xin Gao
Regulatory Affairs Manager
NO. 2258 Chengbei Road
Shanghai, Shanghai 201807
CHINA

Re: K192630
    Trade/Device Name: uWS-MI
    Regulation Number: 21 CFR 892.2050
    Regulation Name: Picture archiving and communications system
    Regulatory Class: Class II
    Product Code: LLZ
    Dated: May 9, 2020
    Received: May 13, 2020

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

Indications for Use

510(k) Number *(if known)*
K192630

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 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 Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time-activity curve.

The 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 or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain.

The 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.

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.

UNITED
IMAGING

SECTION 3

510(k) Summary

510 (k) SUMMARY   K192630

1. Date of Preparation:

May 9, 2020

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 Manager
Tel: +86-021-67076888-5386
Fax: +86-021-67076889
Email: xin.gao@united-imaging.com

3. Identification of Proposed Device

Trade Name: uWS-MI
Common Name: 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: K172998
Device Name: uWS-MI

Reference Device#1
510(k) Number: K183170
Device Name: uWS-CT

Reference device#2
510(k) Number: K173897
Device Name: syngo.via MI Workflows

Reference device#3
510(k) Number: K180077
Device Name: NeuroQ™3.8

Reference device#4
510(k) Number: K123646
Device Name: Emory Cardiac Toolbox™4.0

5. Device Description

uWS-MI is a comprehensive software solution designed to process, review and analyze PET, CT or MR Images. 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 or 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.

This Traditional 510(k) is to request modification for the cleared Picture archiving and communications system (uWS-MI) which have been cleared by FDA via K172998 on April 5, 2018.

The modifications performed on the uWS-MI (K172998) in this submission are due to the change of the basic application (Image Fusion) and the advance applications (Oncology and Dynamic Analysis).

The modifications of Brain Analysis application (NeuroQ™ -- cleared by FDA via K180077) is that it can make comparison between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain.

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 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 Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time-activity curve.

The 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 or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain.

The 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.

7. Technological Characteristic

The technology characteristics of the modified uWS-MI, reflected in this 510(k) submission, do not alter the scientific technology of the devices and are substantially equivalent to those of the predicate and reference devices.

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.

Item	Proposed Device uWS-MI	Predicate Device uWS-MI (K172998)	Remark
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	Same
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 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 Dynamic Analysis application is intended to display PET data and anatomical data such as CT or MR, and supports to do lesion segmentation and output associated time-activity curve.	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 indication for use of the proposed device is expanded and replenished. The proposed device includes more functions under each same application as the predicate device. This difference will not affect the safety and effectiveness.

SECTION 3 Page 5 of 12

| | The 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 or between two studies from the same patient, as well as provide analysis of amyloid uptake levels in the brain. The 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. | 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. | |

Specification

Image communication	Yes	Yes	Same
Hardware /OS	Yes	Yes	Same
Patient Administration	Yes	Yes	Same
Review 2D	Yes	Yes	Same
Review 3D	Yes	Yes	Same
Filming	Yes	Yes	Same
Image Fusion	Yes	Yes	Modify a function under this Application
Inner View	Yes	Yes	Same

Visibility	Yes	Yes	Same
ROI/VOI	Yes	Yes	Same
MIP Display	Yes	Yes	Same
Compare	Yes	Yes	Same
Report	Yes	Yes	Same

1. **SE Discussion for Modified Advanced Applications**

Application	Function name	Proposed device uWS-MI	Predicate Device uWS-MI (K172998)	Remark
Dynamic Analysis	Reframe/Rebin	Yes	Yes	Same
	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
	Manual registration	Yes	Yes	Same
	Auto registration	Yes	Yes	Same
	Dot registration	Yes	Yes	Same
	Fix threshold Segmentation	Yes	Yes	Same
	Adaptive threshold Segmentation	Yes	Yes	Same
	Percentage threshold segmentation	Yes	NO	New Function which will not impact safety and effectiveness.

Application	Function name	Proposed device uWS-MI	Predicate Device uWS-MI (K172998)	Reference device#1: uWS-CT (K183170)	Reference device#2: syngo.via MI Workflows (K173897)	Remark
Oncology	Compare display	Yes	Yes	/	/	Same
	Auto registration	Yes	Yes	/	/	Modified function which will not impact safety and effectiveness.
	Manual registration	Yes	Yes	/	/	Same
	Spread	Yes	Yes	/	/	Same
	Statistical Analysis	Yes	Yes	/	/	Same
	Save	Yes	Yes	/	/	Same
	Fix Segmentation	Yes	Yes	/	/	Same
	Adaptive Segmentation	Yes	Yes	/	/	Same
	Percentage threshold lesion segmentation	Yes	No	/	/	New Function which will not impact safety and effectiveness.
	Lung Nodule Segmentation	Yes	/	Yes	/	Same
	Liver Tumor Segmentation	Yes	/	Yes	/	Same

	Lymph Node Segmentation	Yes	/	/	Yes	Same

Application	Function name	Proposed device uWS-MI	Reference device#3: Neuroq^{TM} (K180077)	Remark
Brain Analysis (Neuroq^{TM})	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
	3D Display	Yes	Yes	Same

Application	Function name	Proposed device uWS-MI	Reference device#4 Syntermed Emory Cardiac Toolbox^{TM} (K123646)	Remark
Cardiac Analysis (Emory Cardiac Toolbox^{TM})	Reconstruction	Yes	Yes	Same
	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

SECTION 3 Page 9 of 12

	Flow Tool	Yes	Yes	Same
	3D	Yes	Yes	Same

8. 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
- Device Hazard Analysis
- Software requirements specification (SRS)
- Software Architecture Design Chart
- Software Development Environment Description
- Software Verification and Validation
- Cybersecurity Documents

Animal Study
No animal study was required.

Clinical Studies
No clinical study was required.

Performance Verification

- Performance Evaluation Report for Lung Nodule and Lymph Nodule Segmentation Algorithms
- Performance Evaluation Report for Non-rigid Registration Algorithm
- Performance Evaluation Report for Percentage Threshold Segmentation Algorithm
- Performance Evaluation Report for PET-MR Auto Registration Image Fusion

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

9. Substantial Equivalent 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 Substantial Equivalent to the predicate device and reference devices.