YIWEI Medical Technology Co., Ltd.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O.box 120-119
Shanghai, 200120
CHINA

February 24, 2023

Re: K213891
Trade/Device Name: RealNow
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 29, 2023
Received: January 30, 2023

Dear Diana Hong:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213891

Device Name
RealNow

Indications for Use *(Describe)*
RealNow is an image processing software package to be used by trained professionals including physicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, analysis and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM compliant imaging devices.

RealNow provides viewing, analysis and communication capabilities for functional and dynamic imaging datasets that are acquired with CT Perfusion imaging protocols.

Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated in the standard DICOM format and may be viewed on existing radiological imaging viewers.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K213891

1. Date of Preparation: 2/23/2023

2. Sponsor Identification

YIWEI Medical Technology Co., Ltd

Room 1001, MaiKelong Building, No. 6, Gaoxin South 6th Road, Dist.Gaoxin, Yuehai Street, Dist.Nanshan, Shenzhen, 518057, China.

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: RealNow
Common Name: Picture Archiving Communications System

Regulatory Information

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

Indication for Use:
RealNow is an image processing software package to be used by trained professionals, such as physicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, analysis and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM compliant imaging devices.

RealNow provides viewing, analysis and communication capabilities for functional and dynamic imaging datasets that are acquired with CT Perfusion imaging protocols.

Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated in the standard DICOM format and may be viewed on existing radiological imaging viewers.

Device Description
RealNow image analysis includes calculation of the following perfusion related parameters:
- Cerebral Blood Flow (CBF)
- Cerebral Blood Volume (CBV)
- Mean Transit Time (MTT)
- Residue function time-to-peak (TMax)
- Arterial Input Function (AIF)

The primary users of RealNow are medical imaging professionals who analyze dynamic CT perfusion studies. The results of image analysis produced by RealNow should be viewed through appropriate diagnostic viewers when used in clinical decision making.

5. Identification of Predicate Device

510(k) Number: K121447
Product Name: RAPID
Manufacturer: iSchemaView, Inc.

6. Non-Clinical Test Conclusion

The software verification and validation testing was conducted on the proposed device

CTP images (Real-World Evidence) are paired uploaded to RealNow and RAPID for perfusion analysis. The parametric maps from the subject device's output have been directly compared to the Rapid outputs in the additional study. The RealNow resulting CBF maps were compared on a pixel by pixel basis to the "ground truth" RAPID CBF maps. Intraclass Correlation Coefficient of the all the pixel values per scan was calculated to assess correlation, of the CBF estimates to the reference values. Volumetry from our device's out to RAPID on the same patient data have been statistically analyzed using MedCalc, and Bland-Altman analysis statistics been performed.

For each scan, parametric map is considered acceptable when the ICC is greater than 0.75, which ICC was calculated per scan from all the voxels within the brain tissue. All Proportion of Acceptable (CBF Parameter Maps, CBV Parameter Maps, MTT Parameter Maps, Tmax Parameter Maps,) more than the 90% (p=0.0009, p=0.0009, p=0.0009, p=0.0196,).The assessment revealed bias is not significant for Rapid_Volume (CBF<20%) Vs RealNow_Volume (CBF<20%) \ Rapid_Volume (CBF<30%) Vs RealNow_Volume (CBF<30%).The assessment revealed a negative bias in Tmax abnormality (mean Rapid_Volume being smaller than mean Tmax volumetry) that increased as the average volume increased. For Proposed Device RealNow mismatch analysis, mismatch volume has been established within the following accuracy parameters:< 50 ml for mismatch volumes (total data); < 25 ml for mismatch volumes (stroke data). Good correlation in behavior between Rapid and RealNow volumetry was found.

Altogether, good agreement and correlation in behavior between Rapid and RealNow was found. The outputs of the subject device are essentially the same as the outputs of the previously cleared RAPID. Subject device is essentially useful for CT brain perfusion reconstruction and analysis, the same as the previously cleared RAPID.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological Characteristics

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K121447	Remark
Product name	RealNow	RAPID	/
Product Code	LLZ	LLZ	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Class	II	II	Same
Indication for Use	RealNow is an image processing software package to be used by trained professionals, such as physicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, analysis and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM compliant imaging devices. RealNow provides viewing, analysis and communication capabilities for functional and dynamic imaging datasets that are acquired with CT Perfusion imaging protocols. Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated in the standard DICOM format and may be viewed on	iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, analysis of brain images. Data and images are acquired through DICOM compliant imaging devices. iSchemaView's RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets that are acquired with CT Perfusion imaging and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of	Different

	existing radiological imaging viewers.	diffusionweighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.	
PACS Functionality			
Basic PACS Functions	Yes	Yes	Same
Computer Platform	Standard “Off-the-Shelf” PC Workstation or VMWare	Standard “Off-the-Shelf” PC Workstation or VMWare	Same
DICOM Compliance	Yes	Yes	
Functional Overview	RealNow is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. RealNow allows viewing and quantification	RAPID is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. RAPID allows viewing and quantification PAPID also has DWI Module to visualize local water diffusion properties from the analysis of diffusionweighted MRI data.	Different
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities.	Acquires medical image data from DICOM compliant imaging devices and modalities.	Same
Data/Image Types	Computed Tomography (CT)	Computed Tomography (CT) Magnetic Resonance Imaging (MRI)	Different
Acquisition and Modalities Features for Tissue Perfusion			
CT	CT Perfusion (CTP)	CT Perfusion (CTP)	Same
Computed Parameter Maps for perfusion CT			
Perfusion CT	Cerebral Blood Flow (CBF)	Cerebral Blood Flow (CBF)	Same
	Cerebral Blood Volume (CBV)	Cerebral Blood Volume (CBV)	Same

	Mean Transit Time (MTT)	Mean Transit Time (MTT)	Same
	Tissue residue function time to peak (TMax)	Tissue residue function time to peak (TMax)	Same
Measurements/Tools			
CT Tools	Arterial Input Function (AIF)	Arterial Input Function (AIF)	Same
	Brain mask	Brain mask	Same
	Export perfusion files to PACS and DICOM file systems	Export perfusion files to PACS and DICOM file systems	Same
	Acquire, transmit, process, and store medical images.	Acquire, transmit, process, and store medical images.	Same

9. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device K121447.