Yukun (Beijing) Technology Co., Ltd.
Qi Wang
Regulatory Affairs Manager
Room 313, 315, Building 3, No.11 Chuangxin Road,
Science Park, Changping District
Beijing, 102200
China

January 19, 2023

Re: K221627
Trade/Device Name: PerfusionGo Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 15, 2022
Received: December 15, 2022

Dear Qi 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/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
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: 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)*

K221627

Device Name
PerfusionGo Plus

Indications for Use *(Describe)*

PerfusionGo Plus 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, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices.

PerfusionGo Plus provides both analysis and communication capabilities for 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 from a raw CTP scan are exported 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.

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510(k) Summary

K221627

1. Submitter

510(k) Submitter

Submitter/Company Name: Yukun (Beijing) Technology Co., Ltd.

Address: Room 313, 315, Building 3, No.11 Chuangxin Road, Science Park, Changping District, Beijing, 102200, China.

Correspondent

Primary Correspondent: Qi Wang.

Title: Regulatory Affairs Manager.

Telephone: +86-10-89735152.

Email: wangqi@shukun.net.

Date Prepared: 12/15/2022

2. Device

Device Type

Trade Name: PerfusionGo Plus.

Common Name: PACS – Picture Archiving and Communications System.

Classification

Classification Regulation: 21 CFR 892.2050;

Class: Class II;

Panel: Radiology;

Product Code: LLZ;

3. Predicate Device

510 (k) number: K180161;

Trade name: Viz CTP;

510(k) submitter/holder: Viz.ai, Inc.

4. Device Description

PerfusionGo Plus is a standalone software package that is comprised of several modules

including Login Module, Image List Module, Image Processing Module and Management Configuration Module. PerfusionGo Plus allows a DICOM-compliant device to send files directly from the image modality, through a node on a local network, or from a PACS server. The device is designed to automatically receive, identify, extract, and analyze a CTP study of the head embedded in DICOM image data. The software outputs parametric maps related to tissue blood flow (perfusion) and tissue blood volume that are written back to the source DICOM. Following such analysis, the results of analysis can be exported manually. The software allows for repeated use and continuous processing of data and can be deployed on a supportive infrastructure that meets the minimum system requirements.

PerfusionGo Plus image analysis includes calculation of the following perfusion related parameters:

- Cerebral Blood Flow (CBF)
- Cerebral Blood Volume (CBV)
- Mean Transit Time (MTT)
- Time-to-peak (TTP)
- Residue function time-to-peak (Tmax)
- Time-density curve (TDC)

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

5. Indications for Use

PerfusionGo Plus 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, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices.

PerfusionGo Plus provides both analysis and communication capabilities for 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 from a raw CTP scan are exported in the standard DICOM format and may be viewed on existing radiological imaging viewers.

6. Comparison of Technological Characteristic with the Predicate Device

Item	Proposed device	Predicate device (K180161)	Analysis
Product Code	LLZ	LLZ	Same
Regulation	21 CFR 892.2050	21 CFR 892.2050	Same
Intended Use/Indications for Use	PerfusionGo Plus 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, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices. PerfusionGo Plus provides both analysis and communication capabilities for 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 from a raw CTP scan are exported in the standard DICOM format and may be	Viz CTP 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 processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices. Viz CTP provides both analysis and communication capabilities for 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 from a raw CTP scan are exported in the standard DICOM format and may be viewed on existing radiological	Same

	viewed on existing radiological imaging viewers.	imaging viewers.	
PACS Functionality			
Basic PACS Functions	Yes	Yes	Same
Computer	Standard “Off-the-Shelf” PC	Standard “Off-the-Shelf” PC	Same
Platform	Workstation or Server	Workstation or VMWare	Different 1
DICOM Compliance	Yes	Yes	Same
Functional Overview	PerfusionGo Plus is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. PerfusionGo Plus allows viewing and quantification.	Viz CTP is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. Viz CTP allows viewing and quantification.	Same
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)	Same
Acquisition and Modalities Features			
CT	CT Perfusion (CTP)	CT Perfusion (CTP)	Same
Computed Parameter Maps			
Perfusion CT	Cerebral Blood Flow (CBF)	Cerebral Blood Flow (CBF)	Same
	Cerebral Blood Volume (CBV)	Cerebral Blood Volume (CBV)	
	Mean Transit Time (MTT)	Mean Transit Time (MTT)	
	Tissue residue function time to peak (Tmax)	Tissue residue function time to peak (Tmax)	
Measurements/Tools			
CT Tools	Time-density Curve (TDC)	Arterial Input Function (AIF)	Different 2
	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

Substantial Equivalence Discussion for Different 1:

The platform of the proposed device is different from that of the predicate device. However,

the difference is in hardware only. The configuration requirements have been provided in instructions of use and the verification and validation tests have been performed on the proposed device and the test results met the acceptance criteria. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

Substantial Equivalence Discussion for Different 2:
The CT tools of the proposed device is different from that of the predicate device. The proposed device displays Time density Curve (TDC), including Arterial input function (AIF) and Venous output function (VOF), although the predicate device displays Arterial input function (AIF) only. However, the verification and validation tests have been performed on the proposed device and the test results met the acceptance criteria. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

7. Performance Data

PerfusionGo Plus complies with DICOM (Digital Imaging and Communications in Medicine), developed by the American College of Radiology and the National Electrical Manufacturers Association. NEM PS 3.1-3.20 (2016).

Yukun performed software verification and validation testing of the device and additional performance testing on a commercially available simulated datasets (digital phantom) generated by simulating tracer kinetic theory, and includes a wide range of clinically relevant values of perfusion parameters as ground truth. Correlations between the output of the PerfusionGo Plus and the ground truth values were calculated.

The results of performance testing showed that the PerfusionGo Plus achieved the pre-established performance goals for each perfusion parameters: CBF, CBV, MTT and Tmax.

Thus, the performance testing demonstrated that the PerfusionGo Plus provides accurate computation of perfusion parameters. Combined with software verification and validation, the performance evaluation demonstrates that the PerfusionGo Plus satisfies all design requirements and specifications.

8. Conclusion

The proposed device is as safe and effective as the predicate device (K180161). The proposed device has the same intended use as its predicate device with respect to CTP functionalities. In addition, the minor technological differences between the proposed

device and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the proposed device is as safe and effective as the predicate for performing CTP analysis. Thus, the PerfusionGo Plus is substantially equivalent.