ArteryFlow Technology Co., Ltd.
℅ Ashley Fu
RA Specialist
459 Qianmo Road, Suite C1-501, Binjiang District,
Hangzhou, Zhejiang 310051
CHINA

November 22, 2022

Re: K220663
Trade/Device Name: AccuCTP
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 18, 2022
Received: October 18, 2022

Dear Ashley Fu:

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
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)*

K220663

Device Name
AccuCTP

Indications for Use *(Describe)*

AccuCTP 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 viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices.

AccuCTP provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), which can visualize and analyze 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.

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.

K220663: 510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1. Submitter's Information

Submitter: ArteryFlow Technology Co., Ltd.

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Secondary correspondent: Ashley Fu, RA Specialist

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Date of preparation: October 18, 2022

2. Device Information

Trade/ Device Name: AccuCTP

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Description: Medical image management and processing system

Regulation number: 892.2050

Classification Product Code: LLZ

3. Predicate Device Information

Manufacturer: iSchemaView, Inc.

Device Name: RAPID

Regulatory Class: Class II

Regulation Number: 892.2050

Classification Product Code: LLZ

510(k) number: K121447

4. Device Description

AccuCTP is a standalone software package that provides visualization and study of changes of tissue perfusion in digital images captured by CT (Computed Tomography). The software provides viewing, quantification, analysis and reporting capabilities, and it allows

repeated use and continuous processing of data and can be deployed on a supportive customer's PC that meets the minimum system requirements.

AccuCTP works with the DICOM compliant medical image data. AccuCTP provides tools for performing the following types of analysis:

- volumetry of threshold maps
- time intensity plots for dynamic time courses
- measurement of mismatch between rCBF and Tmax threshold volumes obtained from the same scan.

5. Indications for Use

AccuCTP 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 viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices.

AccuCTP provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CTP), which can visualize and analyze 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.

6. Performance Data

Software verification and validation testing have been performed in support that AccuCTP satisfies all design specifications and provides accurate computation of output parameters. During the development, potential hazards were controlled by the risk management report, including risk analysis, risk mitigation, verification and validation.

AccuCTP have conducted a phantom test and a validation study of the performance to validate the core algorithm through parameter maps and volumes validation. Besides, filtering and cranial removal have also been validated.

In the phantom test, a group of phantoms was designed to validate the parameter maps and volume compared with ground truth. Parameter map and Volume results were quantitatively analysed and met the pre-defined pass/fail criteria.

In the validation study, a calculation performance validation was conducted to evaluate the agreement between AccuCTP and RAPID CTP in calculating the parameter maps as well as the volume results at the rCBF<30% and Tmax>6s thresholds. Parameter map and Volume results were quantitatively analysed and met the pre-defined pass/fail criteria.

Performance data demonstrates that AccuCTP is as safe and effective as iSchemaView's RAPID for performing CTP analysis.

7. Substantial Equivalence

AccuCTP is a generic tool without being disease-specific and it enables the users to

manually select the outputted threshold values. AccuCTP does not have diagnostic implications and has same intended use compared with predicate device.

AccuCTP shares the same principle of operation and technological characteristics as RAPID (K121447) with respects to CTP functionalities. The minor differences in indications do not alter the intended use of the device, and the minor technological differences raise no new issues of safety or effectiveness. A comparison of the technological characteristics of the predicate and subject device is given in the table below.

Table 1 General Comparison

Parameter	**Subject device** **AccuCTP** **K220663**	**Predicate device** **RAPID** **K121447**
Product Code	LLZ	LLZ
Regulation	21 CFR §892.2050	21 CFR §892.2050
Indications for Use	AccuCTP 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 viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices. AccuCTP provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CTP), which can visualize and analyse 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.	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 and 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 acquired with CT Perfusion (CT-P) 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 diffusion - weighted 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.
Computer Platform	Standard off-the-shelf PC workstation	● Standard off-the-shelf PC workstation/server ● Virtual platform such as VMware
Functional Overview	AccuCTP is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. AccuCTP provides viewing and quantification.	RAPID is a software package that provides for the visualization and study of changes of tissue perfusion and diffusion in digital images captured by CT and MRI. RAPID provides viewing and quantification.
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities
Data/Image Types	DICOM Format	DICOM Format
Acquisition and Modalities Features	CT (CT Perfusion)	● CT (CT Perfusion) ● MRI (Perfusion Weighted Images and Diffusion Weighted Images)
Computed Parameter Maps of Perfusion CT	Cerebral blood flow (CBF)	Yes
	Cerebral blood volume (CBV)	Yes
	Mean transit time (MTT)	Yes
	Tissue residue function time to peak (Tmax)	Yes
CT Tools	Arterial input function (AIF)/Venous output function (VOF)	Yes
	Time-course	Yes
	Brain mask	Yes
	Region of interest (ROI) and Volumetry	Yes
	Motion correction	Yes
	Export perfusion files to local address.	Export perfusion and diffusion files to PACS and DICOM file systems
	Acquire, transmit, process, and	Yes

	store medical images	

8. Conclusion

AccuCTP has same intended use and is as safe and effective as the predicate device RAPID (K121447). The differences between the subject and predicate devices do not raise new questions of safety and effectiveness. Thus, the AccuCTP is substantially equivalent.