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

September 14, 2023

Re: K231353
Trade/Device Name: AccuCTP Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 31, 2023
Received: August 31, 2023

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)*
K231353

Device Name
AccuCTP Pro

Indications for Use *(Describe)*
AccuCTP Pro 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.
AccuCTP Pro 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.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Special 510(k) Summary

This summary of 510(k) 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

Email: fang.fu@arteryflow.com

Date of preparation: August 31, 2023

## 2. Device Information

Trade/ Device Name: AccuCTP Pro

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Name: Medical image management and processing system

Regulation Number: 21 CFR 892.2050

Classification Product Code: LLZ

510(k) number: K231353

## 3. Predicate Device Information

Manufacturer: ArteryFlow Technology Co., Ltd.

Device Name: AccuCTP

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Number: 21 CFR 892.2050

Classification Product Code: LLZ

510(k) number: K220663

## 4. Device Description

AccuCTP Pro is an extension to legally cleared device AccuCTP (K220663).

AccuCTP Pro 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 or a virtual platform that meets the minimum system requirements.

AccuCTP Pro works with the DICOM compliant medical image data. AccuCTP Pro 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 Pro 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.

AccuCTP Pro 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. Technological Characteristic Comparison

AccuCTP Pro is the first update of AccuCTP. Compared to the predicate device AccuCTP (K220663), the intended use of the subject device is equivalent to the intended use of the previously cleared device. The intended user and intended patient population of AccuCTP Pro are not changed. Most important, AccuCTP Pro has the same fundamental scientific technology as the predicate device. The subject and predicate device are based on the same operation principle and algorithm embedded in the software.

Compared to AccuCTP, AccuCTP Pro mainly updated the data transmission mode, simplified manual operation, updated software installation environment (operating systems and virtual platforms).

The technological characteristic comparisons are listed in the following table.

| **Item** | **Proposed device**<br>AccuCTP Pro | **Predicate device**<br>AccuCTP |
|---|---|---|

| **Product Code** | LLZ | LLZ |
|---|---|---|
| **Regulation No.** | 892.2050 | 892.2050 |
| Indications for use | AccuCTP Pro 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.<br><br>AccuCTP Pro 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. | 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.<br><br>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. |
| Operating System Compatibility | Linux operating system and Windows operating system | Linux operating system |
| Basic PACS Function | View, process and analyze medical images. Perform standards PACS functions with respects to querying and listing. | Not supported |
| Computer Platform | ● Standard off-the-shelf PC workstation<br>● Virtual platform, such as VMware | ● Standard off-the-shelf PC workstation |
| Functional Overview | AccuCTP Pro is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. AccuCTP Pro provides viewing and quantification. | 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. |

| | | |
|---|---|---|
| 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) |
| Computed Parameter Maps of Perfusion CT | ● Cerebral blood flow (CBF)<br>● Cerebral blood volume (CBV)<br>● Mean transit time (MTT)<br>● Tissue residue function time to peak (Tmax) | ● Cerebral blood flow (CBF)<br>● Cerebral blood volume (CBV)<br>● Mean transit time (MTT)<br>● Tissue residue function time to peak (Tmax) |
| CT Tools | Arterial input function (AIF)/Venous output function (VOF) | Arterial input function (AIF)/Venous output function (VOF) |
| | Time-course | Time-course |
| | Brain mask | Brain mask |
| | Region of interest (ROI) and Volumetry | Region of interest (ROI) and Volumetry |
| | Motion correction | Motion correction |
| | Export perfusion files to local address | Export perfusion files to local address |
| | Acquire, transmit, process, and store medical images | Acquire, transmit, process, and store medical images |

The outcome of this technological characteristics comparison and risk assessment demonstrates that the minor differences in the technological characteristics do not affect the intended use and the safety or effectiveness of the subject device, AccuCTP Pro, when compared to the legally marketed predicate device AccuCTP (K220663), thus demonstrating the substantial equivalence of the subject device with the predicate device.

## 7. Performance Data to Support Substantial Equivalence

AccuCTP Pro complies with DICOM (Digital Imaging and Communications in Medicine) – Developed by the American college of Radiology and the National Electrical Manufactures Association. NEMA PS 3.1-3.20 (2022d)

The following performance tests were performed on AccuCTP Pro in support of the substantial equivalence determination.

The software modifications to the AccuCTP Pro were implemented under the design controls that are compliant with 21 CFR 820.30. A risk analysis was conducted in accordance with "ISO 14971:2019 Medical devices – Application of risk management to medical devices" to assess the risks and risk mitigations for the device modifications. Based on this risk assessment, the following verification and validation tests were identified and conducted. All tests met the pre-defined acceptance criteria and were passed.

Software Verification Testing: Software requirements derived from the intended use as well as risk control measures are verified by system testing. Requirement coverage matrix of AccuCTP Pro provides traceability between software requirements, software design and the software tests. All requirements are tested, and all results of the tests performed are recorded. The main software verification tests conducted are as follows:

- Tests of importation and exportation of DICOM data
- Tests of automatic selection and calculation of medical image data
- Software management tests
- Case management tests
- Tests of image recalculation and manual adjustment
- Tests of software operating environment

The test results demonstrate that the software is designed to meet the software requirements, and they also demonstrate the performance and safety of the subject device is acceptable.

Cybersecurity Testing: Cybersecurity controls are implemented in accordance with the security control categories and recommendations in guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Device”. Cybersecurity testing including requirement verification testing, static code analysis, and malformed input testing, have been carried out to demonstrate the cybersecurity of our software.

Human Factors Testing: Usability testing of the modified AccuCTP Pro and its operator manual was conducted in accordance with IEC 62366-1:2015, “Application of usability engineering to medical devices”. Fifteen qualified participants performed all critical tasks necessary to validate the usability and user manual without any use errors. The conclusion of the testing was that the AccuCTP Pro can be used safely and effectively by the intended user population. No residual use-related risks were identified.

Labeling Inspection: Labeling inspection was conducted to in accordance with documentation of the company’s quality management system. All inspections were passed.

Phantom test and validation study were completed and reviewed as part of the predicate review (K220663), and the results concluded AccuCTP was safe and effective. As all algorithm and output of the subject device AccuCTP Pro is same as the predicate device AccuCTP, it can be concluded that AccuCTP Pro is acceptable for use. The phantom test and validation study conclusions are not affected by the changes proposed under this 510(k). No additional pre-clinical or clinical data is being provided with this submission.

## 8. Conclusion

AccuCTP Pro has same intended use and algorithm as the predicate device, and it is as safe and effective as AccuCTP (K220663). The verification and validation testing presented demonstrates that the differences between the subject and predicate device do not raise new questions of safety and effectiveness. Thus, the AccuCTP Pro is substantially equivalent.