February 28, 2023

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

Re: K221711
Trade/Device Name: AccuICAS
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: QHA, LLZ
Dated: January 17, 2023
Received: January 18, 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K221711

Device Name
AccuICAS

Indications for Use *(Describe)*
AccuICAS is software intended to be used for performing calculations in X-ray angiographic images of the intracranial vessels. AccuICAS enables neurointerventionalists to obtain quantifications of one or more lesions in the analyzed intracranial vessel segment. In particular, AccuICAS provides:

- Quantitative results of intracranial vessel segments based on a 3D reconstructed model;
- Dimensions of the intracranial vessels and lesions;
- Quantification of the pressure gradient (PG) and pressure ratio (PR) in intracranial vessels.

AccuICAS is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of intracranial vessels in X-ray angiographic images.
When the quantified results provided by AccuICAS are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible clinicians.

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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Tab #06 510(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.

Address: 459 Qianmo Road, Suite C1-501, Binjiang District, 310051 Hangzhou City, Zhejiang Province, China

Phone Number: +86-571-86772567

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Secondary correspondent: Ashley Fu, RA Specialist

Email: fang.fu@arteryflow.com

Date of preparation: February 28, 2023

2. Device Information

Trade/ Device Name: AccuICAS

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Description: Angiographic X-ray system

Regulation number: 892.1600

Classification Product Code: QHA

Subsequent Product Code: LLZ

3. Predicate Device Information

Manufacturer: ArteryFlow Technology Co., Ltd.

Device Name: AccuFFRangio

Regulatory Class: Class II

Regulation Number: 892.1600

Classification Product Code: QHA

Subsequent Product Code: LLZ

510(k) number: K210093

4. Device Description

ArteryFlow AccuICAS is designed as a stand-alone software package to run on a PC. This software can read traditional x-ray angiographic images with DICOM format from the local file directory.

AccuICAS is composed of the following analysis workflows: Image Loading, Frame Selection, Vessel Reconstruction and Hemodynamics Calculation for visualization of the target intracranial vessel segment, quantification of morphological parameters and pressure drop of the intracranial vessel segment. AccuICAS is only for quantitative imaging output but not for diagnosis.

AccuICAS calculates the pressure gradient (PG) and pressure ratio (PR) value for the intracranial vessel. To obtain these values for a specific lesion in an intracranial vessel, the user needs to start with Frame Selection using the same vessel under different angulation. In each of these images, a classic 2D intracranial vessel contour detection is performed, after which a reconstruction of the intracranial vessel segment is obtained in 3D space. Based on the 3D reconstruction and patients' mean arterial pressure, the corresponding pressure gradient (PG) and pressure ratio (PR) value at each position can be calculated.

AccuICAS enables neurointerventionalists to obtain accurate anatomical quantifications of one or more lesions in the analyzed intracranial vessel segment, and to assess the best viewing angles which can be helpful for optimal visualization of the lesion.

AccuICAS's outputs mainly include quantitative dimension results of intracranial vessel and lesions segments based on a 3D reconstructed model and quantification of the pressure gradient (PG) and pressure ratio (PR) in intracranial vessels. Besides, other information provided to the end user also belongs to the outputs, such as display of reference vessels and lesions, display of target vessel lumen contour, 3D reconstructed model of intracranial vessels, the diameter stenosis distribution and PG/PR distributions.

5. Indications for Use

AccuICAS is software intended to be used for performing calculations in X-ray angiographic images of the intracranial vessels. AccuICAS enables neurointerventionalists to obtain quantifications of one or more lesions in the analyzed intracranial vessel segment. In particular, AccuICAS provides:

- Quantitative results of intracranial vessel segments based on a 3D reconstructed model;
- Dimensions of the intracranial vessels and lesions;
- Quantification of the pressure gradient (PG) and pressure ratio (PR) in intracranial vessels.

AccuICAS is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of intracranial vessels in X-ray angiographic images.

When the quantified results provided by AccuICAS are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible

clinicians.

6. Technological Characteristic Comparison

A comparison of the technological characteristics of the predicate and subject device is given in the table below.

Table 1 General Comparison

Item	New device	Predicate device
Device name	AccuICAS	AccuFFRangio
Manufacturer	ArteryFlow Technology Co., Ltd.	ArteryFlow Technology Co., Ltd.
510(k) No.	-	K210093
Product Code	QHA, LLZ	QHA, LLZ
Regulation No.	892.1600	892.1600
Class	II	II
Level of Concern of the software	Moderate	Moderate
Indications for Use		
Intended use / Indications for use	AccuICAS is software intended to be used for performing calculations in X-ray angiographic images of the intracranial vessels. AccuICAS enables neurointerventionalists to obtain quantifications of one or more lesions in the analyzed intracranial vessel segment. In particular, AccuICAS provides: ● Quantitative results of intracranial vessel segments based on a 3D reconstructed model; ● Dimensions of the intracranial vessels and lesions; ● Quantification of the pressure gradient (PG) and pressure ratio (PR) in intracranial vessels. AccuICAS is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of intracranial vessels in X-ray angiographic	AccuFFRangio is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. AccuFFRangio enables interventional cardiologists to obtain quantifications of one or more lesions in the analyzed coronary vessel segment. In particular, AccuFFRangio provides: ● Quantitative results of coronary vessel segments based on a 3D reconstructed model; ● Dimensions of the cardiovascular vessels and lesions; ● Quantification of the pressure drop in coronary vessels. AccuFFRangio is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of

	images. When the quantified results provided by AccuICAS are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible clinicians.	coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease. When the quantified results provided by AccuFFRangio are used in a clinical setting on X-ray images of an individual patient, the results are only intended for use by the responsible clinicians.
Technological Characteristics		
Data type	● X-ray angiographic data in DICOM format (vendor-independent)	● X-ray angiographic data in DICOM format (vendor-independent)
Import of patient data	● Automatically load information from patient's DICOM file; ● Manual through keyboard	● Automatically load information from patient's DICOM file; ● Manual through keyboard
Image display	● 2D X-ray image visualization ● 3D reconstruction of the vessel segment based on 2 X-ray images; ● Graph for actual and reference vessel diameter with vessel longitudinal position; ● Graph for hemodynamics parameter value (PG/PR) with vessel longitudinal position; ● Hemodynamics parameter value (PG/PR) is colored on the 3D reconstructed vessel segment model.	● 2D X-ray image visualization ● 3D reconstruction of the vessel segment based on 2 X-ray images; ● Graph for actual and reference vessel diameter with vessel longitudinal position; ● Graph for AccuFFRangio (FFR) value with vessel longitudinal position; ● AccuFFRangio (FFR) value is colored on the 3D reconstructed vessel segment model.
Centerline and contour definition	● Manual and semi-automatic centerline definition based on contour detection of vessel; ● Contour correction and restriction	● Manual and semi-automatic centerline definition based on contour detection of vessel; ● Contour correction and restriction
Image assessment	● Manual and automatic calibration; ● Vessel dimensions ● Automatic stenosis	● Manual and automatic calibration; ● Vessel dimensions ● Automatic stenosis

	assessment; ● Pressure drop calculation in intracranial vessel	assessment; ● Pressure drop calculation in coronary vessel
Storage of results	● Printout ● Images ● PDF	● Printout ● Images ● PDF
Software operation environment	● Linux Ubuntu 18.04, 64-bit version ● Microsoft Windows 10, 64-bit version ● MacOS 11.4, 64-bit version	● Linux Ubuntu16.04 and 18.04, 32 and 64-bit version ● Microsoft Windows 7, SP1, 32 and 64-bit version ● Microsoft Windows 8.1, 32 and 64-bit version ● Microsoft Windows 10, 32 and 64-bit version

AccuICAS is a quantitative imaging output device as the predicate devices. AccuICAS share the same intended use of performing calculations in X-ray angiographic images with the predicate device AccuFFRangio (K210093). Both products could enable medical professionals to obtain quantifications of one or more lesions based on a 3D reconstructed model and dimensions of vessels. The main outputs of both are morphological parameters and hemodynamics parameters.

Besides, AccuICAS has same software algorithms and technical characteristics with predicate device AccuFFRangio (K210093).

The minor gaps exist in lesion location of indications for use, intended patient population and software operating environment. However, the differences are not critical to the intended use of the device, and do not affect the safety and effectiveness of the device when used as labeled.

7. Performance Data

Software requirements – derived from the intended use and indications for use – as well as risk control measures are verified by system testing. All requirements are tested and all results of the tests performed are summarized in the software test report and especially the requirements coverage matrix of AccuICAS providing traceability between requirements, design and the tests successfully executed.

All outputs of the device have undergone validation to ensure that they support the intended use of the device:

- The segmentation and reconstruction outputs were verified through the verification of the lumen and reference lumen contours and the verification of 3D model.
- Morphological parameters output by AccuICAS was verified using three brass phantoms and a dozen clinical data.
- The diameter stenosis distribution, as well as the PG and PR distributions, were verified using data from several clinical patients with stenosis lesions.

- Hemodynamics calculation was validated by comparing the calculated results with the measured results. The comparison showed good correlation and agreement between the calculated and measured pressure gradients (PG) and pressure ratios (PR).

All of these tests met the predefined criteria, indicating that the AccuICAS algorithm is accurate, and the device is clinically acceptable.

8. Conclusion

Based on the information provided in this submission, AccuICAS shares same intended use, software algorithms and technical characteristics with the predicate device AccuFFRangio (K210093).

Verification and validation testing have produced results consistent with design input requirements. During the development, potential hazards were controlled by a risk management report, including risk analysis, risk mitigation, verification and validation.

ArteryFlow Technology concludes that AccuICAS, intended only for quantitative imaging output but not for diagnosis, is as safe and effective as its predicate device. The difference between the subject and predicate devices do not raise new questions of safety and effectiveness.