March 2, 2023

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

Re: K230303
Trade/Device Name: AccuFFRangio Plus
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: QHA, LLZ
Dated: February 3, 2023
Received: February 3, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230303

Device Name
AccuFFRangio Plus

Indications for Use *(Describe)*
AccuFFRangio Plus is indicated for use in clinical settings where validated and repreproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease.
When the quantified results provided by AccuFFRangio Plus 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 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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Primary correspondent: XIANG Jianping, PhD, General Manager

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Secondary correspondent: Ashley Fu, RA Specialist

Email: fang.fu@arteryflow.com

Date of preparation: February 03, 2023

2. Device Information

Trade/ Device Name: AccuFFRangio Plus

Common Name: Radiological Image Processing System

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

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Number: 892.1600

Classification Product Code: QHA

Subsequent Product Code: LLZ

510(k) number: K210093

4. Device Description

AccuFFRangio Plus is a system that is used to perform calculations in X-ray angiographic images of the coronary arteries. It includes hardware and software (AccuFFRangio) and the hardware of the device which mainly has a display function and provide the software an operation environment. AccuFFRangio Plus is changed from our own legally marketed predicate device AccuFFRangio that is a stand-alone software package. Therefore, the significant change lies in equipping a computer system to the software on a particular mobile cart.

5. Intended Use

AccuFFRangio Plus is a system intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. AccuFFRangio Plus enables interventional cardiologists and researchers to obtain quantifications of one or more lesions in the analyzed coronary vessel segment. In particular, AccuFFRangio Plus 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.

6. Indications for Use

AccuFFRangio Plus is indicated for use in clinical settings where validated and reproducible quantified results are needed to support the assessment of coronary vessels in X-ray angiographic images, for use on individual patients with coronary artery disease.

When the quantified results provided by AccuFFRangio Plus 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.

7. Technological Characteristic Comparison

Compared to the predicate device AccuFFRangio, intended use and indications for use of subject device remain unchanged. The software installed in the subject device is the same as the predicate device. The features and technology of the software part are the same as the predicate device.

The difference lies in the addition of the hardware part. AccuFFRangio Plus has changed to an integrity with software and hardware. The hardware mainly equips a computer system on a mobile cart. The detailed comparisons of differences are provided in the following table:

	Subject Device	**Predicate Device**
Feature	AccuFFRangio Plus (Hardware with software)	AccuFFRangio (Stand-alone software)

Hardware	Monitor	The monitor converts signal outputted from host computer to visible image, and user can operate based on the information displayed.	N/A
	Mouse	Mouse is the input component, user can locate region of interest with the mouse, buttons, and roller.	N/A
	Keyboard	User can input data through keyboard.	N/A
	Host computer	The predicate software is installed within it.	N/A
	Monitor mount	Adjust the height of the monitor when necessary.	N/A
	Equipment shell	It is equipped with power switch, USB port, cable post, heat vent, equipotential terminal and power socket and switch.	N/A
	Casters	Four casters with brake make the product mobile, improving the flexibility and safety.	N/A

8. Performance Data to Support Substantial Equivalence

The hardware modifications to the AccuFFRangio Plus was 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 hardware modifications. Based on this risk assessment, the following verification tests were identified and conducted. All tests met the pre-defined acceptance criteria and were passed.

Electrical Safety Testing: The AccuFFRangio Plus was evaluated and found to be in compliance with the applicable requirements of IEC 60601-1:2012, “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.” All emissions and immunity tests were passed.

Electromagnetic Compatibility Testing: The AccuFFRangio Plus was tested and found to be in compliance with the applicable requirements of IEC 60601-1-2:2014 (4th edition), “Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.”

Hardware Verification Testing: The AccuFFRangio Plus underwent testing per internal specifications through incoming inspections of raw materials and final inspections of finished devices. All hardware requirements of the system were evaluated/tested and found to meet the pre-defined acceptance criteria.

Transportation Testing: The AccuFFRangio Plus was shipped in a padded, wooden box. Transportation testing was conducted in accordance with ASTM D4169-16, “Standard Practice for Performance Testing of Shipping Containers and Systems.” All tests were passed.

Human Factors Testing: Usability testing of the modified AccuFFRangio Plus 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 of AccuFFRangio Plus and user manual without any use errors. The conclusion of the testing was that the AccuFFRangio Plus can be used safely and effectively by the intended user population. No residual use-related risks were identified.

Accelerated Aging Testing: Accelerated aging testing was conducted in accordance with IEC 62506:2013, “Methods for product accelerated testing”. All pre-defined acceptance criteria were met and the service life of the device is validated to be 5 years.

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

No clinical testing was necessary to support the device modifications described in this Special 510(k).

The following testing was leveraged from the predicate device. The results from the predicate were used to support the subject device because the software contained in the AccuFFRangio Plus is the same as the predicate device.

Test	Test description	Applicable standard(s)
Software verification and validation	Software verification testing in accordance with the design requirements to ensure that the software requirements were met. Software validation test to ensure the device meet user needs and perform as intended.	FDA Guidance, “Guidance for the Content of Premarket Submissions for software Contained in Medical Device”
Cybersecurity	Testing to verify Cybersecurity control and management.	Cybersecurity as recommended in FDA

		guidance, “Content of Premarket Submission for Management of Cybersecurity in Medical Device”

9. Conclusion

AccuFFRangio Plus shares the same intended use, and indications for use with AccuFFRangio. Besides, the software application of the device is totally the same as the predicate device. The information and testing presented demonstrate that AccuFFRangio Plus is clinically feasible, and the performance is substantially equivalent to the original ArteryFlow AccuFFRangio cleared device under K210093.