September 10, 2021

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

Re: K210093
Trade/Device Name: AccuFFRangio
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: QHA, LLZ
Dated: August 12, 2021
Received: August 16, 2021

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K210093

Device Name
AccuFFRangio

Indications for Use *(Describe)*

AccuFFRangio 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 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 SMDA 1990 and 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

Primary correspondent: XIANG Jianping, PhD, General Manager

Email: jianping.xiang@arteryflow.com

Secondary correspondent: Ashley Fu, Registration engineer

Email: fang.fu@arteryflow.com

Date of preparation: January 05, 2021

2. Device Information

Trade/ Device Name: AccuFFRangio

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: Medis medical imaging systems bv

Device Name: QANGIO XA 3D

Regulatory Class: Class II

Regulation Number: 892.1600

Classification Product Code: QHA

Subsequent Product Code: LLZ

510(k) number: K182611

4. Device Description

ArteryFlow® AccuFFRangio 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.

The AccuFFRangio is composed of the following analysis workflows: Image Loading, Frame Selection, Vessel Reconstruction, QCA Vessel Quantification, and AccuFFRangio Calculation for visualization of the target coronary segment, quantification of the stenosis and pressure drop of the coronary segment. The AccuFFRangio parameter is only for quantitative imaging output but not for diagnosis and the AccuFFRanigo product has a moderate level of concern.

The user can calculate the pressure drop and AccuFFRangio (FFR) value for the coronary vessel. To obtain these values for a specific lesion in a coronary vessel, the user has to start with Frame Selection using two angiographic images from different views. In each of these images, a classic 2D coronary contour detection is performed, after which a reconstruction of the coronary segment is obtained in 3D space. Based on the 3D reconstruction and user input of the aortic pressure, the pressure drop and AccuFFRangio value can be calculated.

AccuFFRangio enables interventional cardiologists to obtain accurate anatomical quantifications of one or more lesions in the analyzed coronary segment, and to assess the best viewing angles which can be helpful for optimal visualization of the lesion during percutaneous coronary intervention (PCI) treatment.

Results can be displayed and generated by the software, which contains patient information, imaging of actual and reference vessel boundaries, dimensions of the vessel sizing, pressure drop, and AccuFFRangio value. The results can be export in PDF format. This functionality is independent of the type of vendor acquisition equipment.

5. Intended Use

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.

6. Indication for Use

AccuFFRangio 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 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.

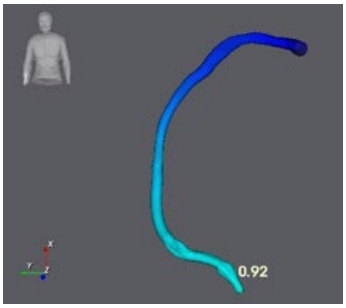
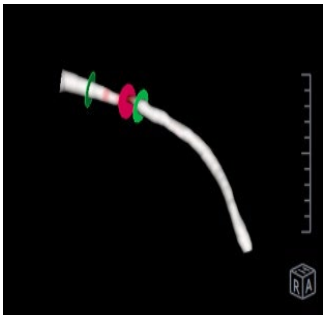
7. Technological Characteristic Comparison

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	AccuFFRangio	QANGIO XA 3D
Manufacturer	ArteryFlow Technology Co., Ltd.	Medis medical imaging systems bv
510(k) No.	-	K182611
Product Code	QHA, LLZ	QHA, LLZ
Regulation No.	892.1600	892.1600
Class	II	II
Level of Concern of the software	Moderate	Moderate
Intended Use and Indications for Use		
Intended Use	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.	QANGIO XA 3D is software intended to be used for performing calculations in X-ray angiographic images of the coronary arteries. QANGIO XA 3D enables interventional cardiologists and researchers to obtain quantifications of one or more lesions in the analyzed coronary vessel segment. In particular, QANGIO XA 3D 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.
Indication for use	AccuFFRangio 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.	QANGIO XA 3D 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

	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.	artery disease. When the quantified results provided by QANGIO XA 3D 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 with embedded ECG signal; ● 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.	● 2D X-ray image visualization with embedded ECG signal; ● 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 QFR (FFR) value with vessel longitudinal position; ● QFR (FFR) value is colored on the 3D reconstructed vessel segment model.
Centerline and contour definition	● Manual and semi-automatic centerline definition based contour detection of coronary vessel; ● Contour correction and restriction	● Manual and semi-automatic centerline definition based contour detection of coronary and peripheral vessel; ● Contour correction and restriction
Image assessment	● Manual and automatic calibration; ● Vessel dimensions (diameters, areas, lengths); ● Automatic stenosis assessment; ● Pressure drop calculation in coronary vessel	● Manual and automatic calibration; ● Vessel dimensions (diameters, areas, lengths); ● Automatic stenosis assessment; ● Pressure drop calculation in coronary vessel

FFR calculation	AccuFFRangio provides a quantification parameter called AccuFFRangio.	QANGIO XA 3D provides a quantification parameter called QFR.
Storage of results	● Printout ● Images ● PDF	● Printout ● Images ● PDF
Different technological Characteristics		
Gap 1	With ECG display in the image pane	ECG display in a separate pane
Gap 2	The vessel is colored by stenosis percentage in red to blue	The vessel is colored by stenosis percentage in red to white
Gap 3	When visualizing the reconstructed vessel segment, there is a body icon to show the relative position for the vessel segment. 	In QAngio XA 3D, there is a box icon to show the relative position for the vessel segment. 
Gap 4	In the calculated vessel FFR distribution, users can easily point the position by the curser and the specific AccuFFRangio value will show up.	In QAngio XA 3D, the user needs to move four “checking disk” and look at the FFR value in the left-bottom window.
Gap 5	Software operation environment: ● 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 ● Linux Ubuntu16.04 and 18.04, 32 and 64-bit version	Software operation environment: ● 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 ● Microsoft Windows Server 2008 R2, SP1, 64-bit version ● Microsoft Windows Server 2012 R2, 64-bit version ● Microsoft Windows Server 2016, 64-bit version

AccuFFRangio has the same intended use and indications for use as the predicate devices QANGIO XA 3D (K182611). The basic features in technological characteristics are the same, such as same types of data format, same method for importing patient data, similar

display of image, same definition for centerline and contour, same method for Image assessment, same output for 3D reconstruction and the calculation of the pressure drop, etc.

AccuFFRangio is a quantitative imaging output device, like the QANGIO XA 3D. Though above five differences concerning the display pattern (gap 1), display interface (gap 2-3), specific operate method on showing result (gap 4) and software operating system (gap 5) do exist, they do not affect the function and safety of AccuFFRangio.

8. Performance Data

System 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 statement and especially the requirements coverage matrix of AccuFFRangio providing traceability between requirements and the tests successfully executed.

The main functionality (including 3D vessel reconstruction, the calculation of the pressure drop and AccuFFRangio) have all been validated:

- 3D vessel reconstruction: A phantom study had been implemented by using three different types stenosis of brass model. This phantom test was to evaluate the accuracy of the 3D quantitative coronary angiography (QCA) of AccuFFRangio software. The following software technical parameters were validated, namely, lesion length accuracy, diameter stenosis accuracy, area stenosis accuracy, minimal lumen diameter accuracy and reference diameter accuracy. This demonstrated that the quantitative coronary angiography for coronary vessel have similar performance compare to the predicate device QAngio XA 3D (K182611).
- AccuFFRangio calculation: To confirm the performance of the pressure drop and AccuFFRangio (FFR) calculation in the coronary vessel, a series of X-ray angiographic dataset with known pressure drops were analyzed. The functionality of pressure drop and AccuFFRangio calculation for the new device is based on 3D reconstruction out of two angiographic images. The results, including accuracy, sensitivity, specificity, positive predictive value and negative predictive value for per-vessel were calculated. The results demonstrated that the quantification of AccuFFRangio in coronary vessel have similar performance compare to the QFR by the predicate device QAngio XA 3D (K182611).

9. Conclusion

AccuFFRangio product manufactured by our company shares the same intended use, and indications for use with QAngio XA 3D by Medis.

Testing, validation and verification have produced results consistent with design input requirements. AccuFFRangio is a software-only device for which there are no applicable mandatory performance standards.

During the development, potential hazards were controlled by a risk management report, including risk analysis, risk mitigation, verification and validation.

ArteryFlow technology concludes that the AccuFFRangio is only for quantitative imaging

output but not for diagnosis, and it is a safe and effective medical device as its predicate device. The use of AccuFFRangio does not change the intended use of X-ray angiography acquisition, nor does the use of this software results in any new potential hazards.