December 9, 2019

CathWorks Ltd
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K192442
Trade/Device Name: FFRangio System
Regulation Number: 21 CFR 870.1415
Regulation Name: Coronary Vascular Physiologic Simulation Software Device
Regulatory Class: Class II
Product Code: QEK
Dated: November 14, 2019
Received: November 18, 2019

Dear Sheila Hemeon-Heyer:

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,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
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)*
K192442

Device Name

FFRangio™ System

Indications for Use *(Describe)*

CathWorks FFRangio™ is a software device for the clinical quantitative and qualitative analysis of previously acquired angiography DICOM data for patients with coronary artery disease. It provides FFRangio™, a mathematically derived quantity, computed from simulated blood flow information obtained from a 3D computer model, generated from coronary angiography images. FFRangio™ analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis are provided as a supportive aid for qualified clinicians in the evaluation and assessment of coronary arteries physiology. The results of CathWorks FFRangio™ are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional evaluation.

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.

Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted per the requirements of 21 CFR 807.92.

A. Submitter:

Heyer Regulatory Solutions LLC
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Amherst, MA 01004-2151
Contact: Sheila Hemeon-Heyer
Sheila@heyer-regulatory.com

B. Manufacturer:

CathWorks, Ltd.
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C. Date Prepared: November 12, 2019

D. Device Name and Classification Information:

Trade Name:	FFR_{angio}™ System
Common/Usual Name:	Digital FFR System
Classification Name:	Coronary Vascular Physiologic Simulation Software
Regulation:	21 CFR 870.1415
Product Code:	QEK
Review Panel:	Cardiovascular
Class:	II

E. Predicate Device(s): K182149 FFR_{angio}™ System

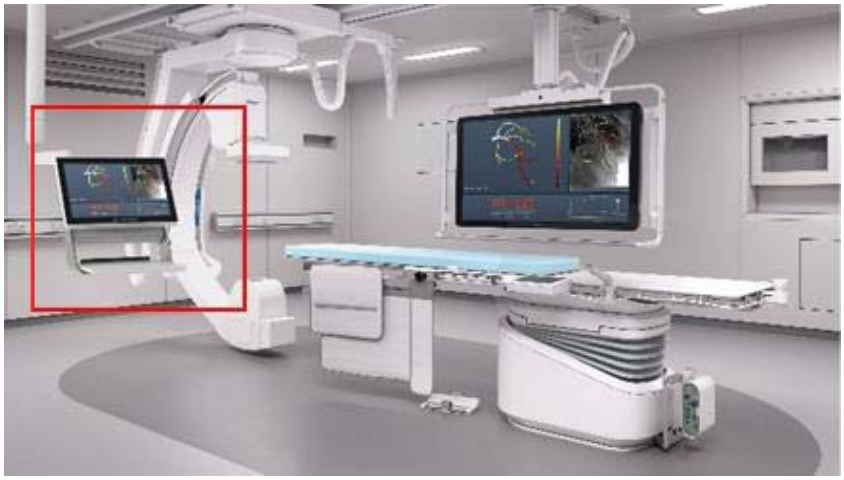
F. Summary Device Description:

FFR_{angio} uses standard angiographic images that are retrieved from the X-ray Imaging System (C-arm) in DICOM format. The user selects the images and, following the system prompts, marks key features on the images including the target lesion, ostium location, main vessel, target vessel, and its side branches. The system then matches the corresponding vessels among the projections and generates a 3D computer model of the vessels. The 3D model is used for blood flow analysis and determination of the FFR_{angio}.

The modified FFR_{angio} system, designated as model FAU4000, consists of the following components:

- Touch screen control console located either as a fixed installation in the cath lab on an extension arm mounted on the wall or from the ceiling, or on a desktop or mobile cart in the cath lab or control room
- Processing Unit located in the cath lab machine room / control room
- 3D Mouse located at the patient bedside
- Connection Box located in either the cath lab or control room

The system supports optional visual media output to the cath lab main displays, so the system GUI may be observed on both the system's Console display and on the cath lab's main display (boom monitor).



G. Indications for Use Statement:

CathWorks FFR_{angio} is a software device for the clinical quantitative and qualitative analysis of previously acquired angiography DICOM data for patients with coronary artery disease. It provides FFR_{angio}, a mathematically derived quantity, computed from simulated blood flow information obtained from a 3D computer model, generated from coronary angiography images. FFR_{angio} analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis are provided as a supportive aid for qualified clinicians in the evaluation and assessment of coronary arteries physiology. The results of CathWorks FFR_{angio} are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional evaluation.

H. Comparison with Predicate Device

This is a Special 510(k) for hardware and software changes to the previously cleared FFR_{angio}™ System. These changes do not alter the fundamental scientific technology of

the device or the indications for use. There have been no changes to the underlying data processing algorithm. The changes are implemented primarily to improve the system ease of use.

The table below provides a technological comparison between the modified and previously cleared FFR_{angio} Systems. Discussion of the differences is provided following the table.

	Predicate FFR_{angio}™ (model FAU1000)	**Modified FFR_{angio}™ (model FAU4000)**
Indications for Use	CathWorks FFR_{angio} is a software device for the clinical quantitative and qualitative analysis of previously acquired angiography DICOM data for patients with coronary artery disease. It provides FFR_{angio}, a mathematically derived quantity, computed from simulated blood flow information obtained from a 3D computer model, generated from coronary angiography images. FFR_{angio} analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis are provided as a supportive aid for qualified clinicians in the evaluation and assessment of coronary arteries physiology. The results of CathWorks FFR_{angio} are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional evaluation.	CathWorks FFR_{angio} is a software device for the clinical quantitative and qualitative analysis of previously acquired angiography DICOM data for patients with coronary artery disease. It provides FFR_{angio}, a mathematically derived quantity, computed from simulated blood flow information obtained from a 3D computer model, generated from coronary angiography images. FFR_{angio} analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis are provided as a supportive aid for qualified clinicians in the evaluation and assessment of coronary arteries physiology. The results of CathWorks FFR_{angio} are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional evaluation.
System overview	Computer system with software that constructs and displays a 3D computer model of the coronary arteries to simulate blood flow	Computer system with software that constructs and displays a 3D computer model of the coronary arteries to simulate blood flow
System components and setup	LCD screen with keyboard and mouse Hewlett-Packard HPz240 Tower Workstation System on a moveable cart in the cath lab Connections to enable display on the cath lab boom monitor	Touchscreen console with virtual keyboard and mouse Hewlett-Packard Z2 Tower Workstation Workstation in the cath lab control room or machine room and console in a fixed location or on moveable cart in the cath lab or control room Connections to enable display on the cath lab boom monitor Optional 3D mouse mounted on the patient bedrail used to rotate and zoom the 3D vessel image that appears on the Results screen on the cath lab main display. Not used during FFR_{angio} processing. Optional connection box, which can be located in the control room or in the cath lab for optional additional display on an AUX monitor in the control room by means of a DVI Video cable or for Bluetooth

	Predicate FFR$_{angio}$™ (model FAU1000)	Modified FFR$_{angio}$™ (model FAU4000)
		communication between the 3D mouse and console if the console is located outside of the cath lab procedure room.
Image source	Standard DICOM angiographic images taken in Cath Lab	Standard DICOM angiographic images taken in Cath Lab
Software controlled	Yes	Yes
Real-time results	Yes	Yes
Sensitivity*	93.5% (lower 95% CI, 87.8%)	93.5% (lower 95% CI, 87.8%)
Specificity*	91.2% (lower 95% CI, 86.0%)	91.2% (lower 95% CI, 86.0%)

*Sensitivity and specificity are the per vessel estimates as determined from the FFR$_{angio}$ pivotal clinical study. The changes described in this Special 510(k) do not affect the system sensitivity or specificity,

Discussion of Differences

The modified FFR$_{angio}$ System has the same intended use/indications for use, uses the same imaging source for system input (standard core lab angiograms), and same data processing algorithms to determine the FFR$_{angio}$. The system components and system operation are essentially the same as the originally cleared system.

The key differences between the original and modified FFR$_{angio}$™ Systems are:

- Both the processing unit and console components of the original system were resident on a mobile cart in the cath lab. The modified system offers an approach that allows for different physical configurations, i.e., there can be a physical separation between the system components when the processing unit is located in the cath lab control room and the console is installed in the cath lab or the system units can be located together in the control room.
- The original system used an LCD screen with separate keyboard and mouse while the modified console is a touch screen with mouse.
- The modified system offers an optional 3D mouse mounted on the patient bed rail that allows the physician to rotate and zoom to view the 3D coronary vessel image that appears on the Results screen after FFR$_{angio}$ processing. The 3D mouse communicates with the system console via wireless Bluetooth.
- An optional connection box is available for the modified system that enables display on an AUX monitor in the control room by means of a DVI Video cable or for Bluetooth communication between the 3D mouse and console if the console is located outside of the cath lab procedure room.

In addition, minor changes have been made to the workflow software and user interface to reduce idle time and improve the user experience. None of these changes affect the

indications for use, fundamental scientific technology, or raise new questions of safety or effectiveness of the CathWorks FFR_{angio}.

I. Performance Data to Support Substantial Equivalence

The hardware and software modifications to the FFR_{angio} System were implemented under the CathWorks design controls that are compliant with 21 CFR 820.30. A risk analysis was conducted in accordance with ISO 14971:2007 Medical devices - Application of risk management to medical devices to assess the risks and risk mitigations for the device hardware and software 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.

Software Validation: Software documentation consistent with FDA's guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 11, 2005, for moderate level of concern software including a comprehensive risk analysis of the changes, software verification and validation, off-the-shelf software integrity, and cybersecurity considerations. The software in the FFR_{angio} complies with ISO 62304:2015 Medical device software - Software life cycle processes.

Electrical Safety Testing: The FFR_{angio} computer system components were evaluated and found to be in compliance with the applicable requirements of IEC 60601-1:2005 (3rd Edition) +C1:2006 +C2:2007 +A1:2012, "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance." All emissions and immunity tests were passed.

Electromagnetic Compatibility Testing: The FFR_{angio} computer system components were 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."

FCC Compliance Testing: The 3D Mouse and receiver were tested and found to be in compliance with FCC Part 15, Subpart C, Sections 15.203, 15.205, 15.207, 15.209, and 15.249 for RF wireless communications systems operating in frequency range 2404-2477 Mhz. Measurements were in compliance with ANSI C63.4-2003 American National Standards of Measurement of Radio-Noise emissions from Low-Voltage Electrical and Electronic Equipment in the range of 9 KHz to 40 GHz.

Hardware Verification Testing: The FFR_{angio} computer system components and system connections underwent type testing per an internal CathWorks protocol. All hardware requirements of the system were evaluated/tested and found to meet the pre-defined acceptance criteria.

Transportation Testing: The FFR_{angio} computer system components and accessories are shipped in a padded, wooden box. Environmental conditioning was conducted in accordance with ASTM D4332-14 "Standard Practice for Conditioning Containers, Packages, or Package Components." 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 FFR_{angio} system and its operator manual was conducted in accordance with ANSI/AAMI/IEC 62366-1:2015, "Application of usability engineering to medical devices" and the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices," February 3, 2016. Fifteen participants performed all of the tasks necessary to process an FFR_{angio} using the modified workflow and user manual while the test moderator observed each user performance throughout the individual steps. This was followed by a knowledge-based assessment of the labeling, warnings and precautions and analysis process. All critical tasks identified for the use of the FFR_{angio} system were completed in the usability testing without any use errors. The conclusion of the testing was that the FFR_{angio} system can be used safely and effectively by the intended user population. No residual use-related risks were identified.

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

J. Compliance with Special Controls for 21 CFR 870.1415

Special Controls (abbreviated from regulation)	How Fulfilled
1) Adequate software verification and validation based on comprehensive hazard analysis, with identification of appropriate mitigations, must be performed.	The changes to the FFR_{angio} system software were developed, implemented and tested in accordance with ISO 62304:2006 Medical device software -- Software life cycle processes and included comprehensive hazard analysis, identification of appropriate risk mitigations, and software testing appropriate to verify the changes in the workflow software. There were no changes to the FFR_{angio} software algorithms. Documentation as required by FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for moderate level of concern software was provided.
2. Adequate non-clinical performance testing must be provided to demonstrate the validity of computational modeling methods for flow measurement.	Not applicable. There have been no changes to the computational modeling methods for flow measurement.
3. Clinical data supporting the proposed intended use must be provided.	Not applicable. None of the changes documented in this Special 510(k) required clinical testing.

Special Controls (abbreviated from regulation)	How Fulfilled
(4) Adequate validation must be performed and controls implemented to characterize and ensure consistency (repeatability and reproducibility) of measurement output.	Not applicable. None of the changes documented in this Special 510(k) could affect the repeatability and reproducibility of the measurement output.
(5) Human factors evaluation and validation must be provided to demonstrate adequate performance of the user interface to allow for users to accurately measure intended parameters, particularly where parameter settings that have impact on measurements require significant user intervention.	A human factors study was conducted in accordance with FDA's Guidance Applying Human Factors and Usability Engineering to Medical Devices, 2016. All critical tasks identified for the use of the FFR_{angio} system were completed in the usability testing without any use errors. The conclusion of the testing was that the FFR_{angio} system can be used safely and effectively by the intended user population. No residual use-related risks were identified.
(6) Device labeling must be provided that adequately describes the following: (i) The device's intended use, (ii) Appropriate warnings (iii) Key assumptions (iv) The measurement performance of the device for all presented parameters (v) A detailed description of the clinical study subjects and results (vi) A detailed description of the analysis procedure using the device and any data features that could affect accuracy of results.	The device instructions for use include all of the elements required by this special control, including: • Intended use statement, the device mechanism of action and intended patient population • Appropriate warnings and precautions for safe use of the device, including factors that could adversely affect the device output and cautions to use the device output in context with other clinical factors for patient care • Limitations describing patient populations and lesion types for which the safety and effectiveness of FFR_{angio} has not been evaluated • Instructions for use providing guidelines for the compatible image acquisition systems and the required criteria for the images to process the FFR_{angio}. • Detailed steps for the system operation and analysis procedures • A detailed summary of the FAST-FFR clinical study protocol

K. Conclusion

The information and testing presented in this 510(k) demonstrate that the modified CathWorks FFR_{angio} is substantially equivalent to the original CathWorks FFR_{angio} cleared under K182149.