October 14, 2022

HeartFlow, Inc.
Windi Hary
Chief Regulatory and Quality Officer
1400 Seaport Boulevard, Building B
Redwood City, California 94063

Re: K213857
Trade/Device Name: HeartFlow Analysis
Regulation Number: 21 CFR 870.1415
Regulation Name: Coronary Vascular Physiologic Simulation Software Device
Regulatory Class: Class II
Product Code: PJA, LLZ
Dated: October 11, 2022
Received: October 13, 2022

Dear Windi Hary:

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

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213857

Device Name
HeartFlow Analysis

Indications for Use *(Describe)*
The HeartFlow Analysis is an AI-based medical device software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for patients with suspected coronary artery disease. It provides anatomic data, plaque identification and characterization, as well as the calculations of FFRCT, a coronary physiological simulation, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. The HeartFlow Analysis is intended to support the risk assessment and functional evaluation of coronary artery disease.

The HeartFlow Analysis is provided to support qualified clinicians to aid in the evaluation and risk assessment of coronary artery disease. The HeartFlow Analysis is 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 judgment.

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.

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This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

1 Submitter Information

Submitter / Manufacturer Name:	HeartFlow, Inc. 331 E. Evelyn Ave Mountain View, CA 94041
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Date Prepared:	April 20, 2022

2 Device Identification

Product Name	HeartFlow Analysis	**Common Name**	FFRct
Product Feature Description	**Product Code**	**Classification**	**Classification Name**
FFRct	PJA-Primary	*870.1415*	Coronary vascular physiologic simulation software device
PreRead (Anatomy extracted from FFRct 3D model) and system plaque volumes	LLZ-Secondary	*892.2050*	Medical image management and processing system

Plaque characterization presented with FFRct model (automated AI/ML detection)	LLZ-Secondary	*892.2050*	Medical image management and processing system
Planner	PJA-Secondary	*870.1415*	Coronary vascular physiologic simulation software device

3 Predicates

HeartFlow FFR_{CT} v3 (K203329) is the identified primary predicate and Autoplaque add-on ORS Visual (K122429) is an additional predicate for this submission.

4 Device Description

The HeartFlow Analysis is an AI-based medical device software developed for the clinical quantitative and qualitative analysis of CT DICOM data. It is a tool for the analysis of CT DICOM-compliant cardiac images and data, to assess the anatomy and function of the coronary arteries in the risk stratification and evaluation of coronary artery disease.

The software displays coronary anatomy and functional information using graphics and text, including computed and derived quantities of percent stenosis, plaque volumes, blood flow, pressure and velocity, to aid the clinician in the assessment and treatment planning of coronary artery disease.

The HeartFlow Analysis is performed on previously physician-acquired image data and is unrelated to acquisition equipment and clinical workstations.

5 Indications for Use

The HeartFlow Analysis is an AI-based medical device software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for patients with suspected coronary artery disease. It provides anatomic data, plaque identification and characterization, as well as the calculations of FFRCT, a coronary physiological simulation, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. The HeartFlow Analysis is intended to support the risk assessment and functional evaluation of coronary artery disease.

The HeartFlow Analysis is provided to support qualified clinicians to aid in the evaluation and risk assessment of coronary artery disease. The HeartFlow Analysis is 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 judgment.

6 Technological Characteristics of Device

The HeartFlow Analysis is a software medical device that allows for the quantitative and qualitative analysis of Coronary Computed Tomography Angiography (cCTA). The predicates and this product have the same technological characteristics.

The core technology remains unchanged from the primary predicate and continues to be trained using deep learning (AI and machine learning) since 2015, to incorporate learnings from the volumes of CT data and studies. All algorithms are then frozen and validated prior to product release. There are no differences between the subject device and the predicates with respect to intended use.

Table 5-1. Predicate Device Comparison

	FFR_{CT} v3 (primary predicate)	**Autoplaque (predicate)**	**FFR_{CT} v3.plus**
510(k)	K203329	K122429	K213857

	FFR_{CT} v3 (primary predicate)	**Autoplaque (predicate)**	**FFR_{CT} v3.plus**
Manufacturer	HeartFlow, Inc.	Object Research Systems, Inc.	HeartFlow, Inc.
Regulation Number	870.1415	892.2050	870.1415
Regulation Name	Coronary Physiologic Simulation Software Device	System, Image Processing, Radiological	Coronary Physiologic Simulation Software Device
Classification	Class II	Class II	Class II
Device Common Name	HeartFlow FFR_{CT}	Image Processing System, Radiology,Software PACS	HeartFlow Analysis
Product Code	PJA	LLZ	PJA
Functions	-Extract anatomic data from digital cardiac images for the display and visualization of the anatomy of patient's coronary arteries -Compute FFRct	-Users of Autoplaque can edit the lumen and vessel walls of the suggested segmentation. -Users are provided with image viewing tools to aid in their analysis. -Plaque and stenosis measurements are output based on the combination of fully user-editable segmentation and user-placed demarcations of coronary artery characteristics.	-Extract anatomical *and plaque* data from digital cardiac images for the display and visualization of the anatomy of patient's coronary arteries -Compute FFRct
Intended use	-Review of CT angiographic images to confirm the coronary vessels -Semi-automated tools for extraction of anatomic data (including heart structures) for coronary physiologic simulation to aid in diagnosis of coronary artery disease	-Provide a non-invasive application to analyze coronary anatomy and pathology -Post processing application option for the ORS visual platform (K100335). -A non-invasive diagnostic reading software add-on intended for use by cardiologists and radiologists as an	-Review of CT angiographic images to confirm the coronary vessels -Semi-automated tools for extraction of anatomic data (including heart structures) for coronary physiologic simulation to aid in diagnosis of coronary artery disease -Centerline detection

	FFR_{CT} v3 (primary predicate)	**Autoplaque (predicate)**	**FFR_{CT} v3.plus**
	-Centerline detection -Provides additional data derived from coronary CT anatomy and pathology -Provide simulated hemodynamic information	interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques. -ORS Visual software (K100335) and the Autoplaque add-on must be installed on a suitable commercial computer platform.	-Provides additional data derived from coronary CT anatomy and pathology -Provide simulated hemodynamic information
Data source (input)	CT	CT	CT
Output/ Accessibility	Graphic and text results of coronary anatomy and simulated data are accessed via a device with internet connectivity	Graphic and text results provided on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.	Graphic and text results of coronary anatomy and simulated data are accessed via a device with internet connectivity
Physical characteristics	-Non-invasive software package -DICOM compatible	-Software installed and used by the user -Suitable commercial computer platform	-Non-invasive software package -DICOM compatible
Safety	Clinician review and assessment of analysis prior to use as supplemental diagnostic aid	Clinician editable, review, and assessment of analysis prior to use as supplemental diagnostic aid	Clinician review and assessment of analysis prior to use as supplemental diagnostic aid

Table 5-2. Predicate Device Feature Comparison

Feature	**FFRct v3 (primary predicate)**	**Autoplaque (predicate)**	**FFRct v3.plus (subject)**
Presentation of CT images for confirmation of extracted model	x		x
Automatic extraction of anatomic data from CT images for analysis	x	x	x
Modeled stenosis and plaque* information		x (user edit)	x

Volume rendering based on centerlines	x		x
Automatic/Semi-automatic lumen boundary determination	x	x (user edit)	x
Annotate, tag, measure and record selected views	x	x (user edit)	x
View the coronary vessels	x	x (user edit)	x
Modify anatomic model to remove luminal narrowing(s)	x		x
Expose interim calculations used as input of FFRct (e.g., mass and volume)	x		x
Calculate functional parameters of the heart (e.g., Fractional Flow Reserve, %myo)	x		x
Visualize plaque information*		x (user edit)	x
Graphic and text results	x	x	x

*Anatomical plaque calculation and visualization is supported by comparison to the Autoplaque predicate device

7 Summary of Studies

The software was designed, developed, tested and validated according to written procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance.

Validation studies included stress testing, and repeatability testing to ensure the safety and effectiveness of the device. Software and medical device design validation has been completed. Medical device design included testing and evaluation using previously acquired diagnostic images received through HeartFlow sponsored clinical trials.

Summaries of pre-clinical studies were reviewed as part of a prior predicate review (K161772, the original predicate of K182035/K190925/K203329). The results concluded the device was acceptable for use.

Results of all current and previously referenced testing conclude the device is acceptable for use.

8 Conclusion

The conclusions drawn from the testing demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in section 2 above.