December 6, 2018

HeartFlow, Inc
Windi Hary
Senior Vice President, Clinical, Quality and Regulatory
1400 Seaport Boulevard
Building B
Redwood City, California 94063

Re: K182035
Trade/Device Name: FFRct v 2.18
Regulation Number: 21 CFR 870.1415
Regulation Name: Coronary Vascular Physiologic Simulation Software Device
Regulatory Class: Class II
Product Code: PJA
Dated: November 2, 2018
Received: November 6, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.12.06 12:29:07 -05'00'

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K182035

Device Name: FFR_{CT} v 2.18

HeartFlow FFR_{CT} is a coronary physiologic simulation software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for clinically stable symptomatic patients with coronary artery disease. It provides $FFR_{CT,}$ a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. FFR_{CT} analysis is intended to support the functional evaluation of coronary artery disease.

The results of this analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow FFR_{CT} 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 judgment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

Over-the-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

5.0 510(K) SUMMARY

This 510(k) summary of device performance information is submitted in accordance with the requirements of 21 CFR Part 807.87(h). There is no change from the performance submitted as part of the predicate K161772.

5.1 Submitter Information

Submitter / Manufacturer Name:	HeartFlow, Inc. 1400 Seaport Boulevard, Building B Redwood City, CA 94063
Contact Person:	Windi Hary, RAC Senior Vice President, Clinical, Quality and Regulatory HeartFlow, Inc. 1400 Seaport Boulevard, Bldg B Redwood City, CA 94063 T +1 (650) 241-1250 F +1 (650) 368-2564 whary@heartflow.com
Date Prepared:	June 26, 2018

5.2 Device Identification

Device Name:	FFR_{CT} v2.18
Device Trade Name:	FFR_{CT} v2.18
Common Name:	HeartFlow FFR_{CT}
Classification Name:	Coronary Physiologic Simulation Software Device
Product Code:	PJA
Product Class:	Class II (21 CFR 870.1415)

5.3 Predicate and Description of Change

HeartFlow FFR_{CT} (K161772) is the identified predicate for this submission, there is no change to the product functionality, architecture, or design. Changes included in this submission are to clarify the product boundary at the application programming interface (API).

There is no change to the product functionality, architecture, or design, however, all of the changes will be reflected in appropriate labeling.

5.4 Device Description

FFR_{CT} is coronary physiologic simulation 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.

The software displays the anatomy combined with functional information using graphics and text, including computed and derived quantities of blood flow, pressure and velocity, to aid the clinician in the assessment of coronary artery disease.

FFR_{CT} is independent of imaging equipment, imaging protocols and equipment vendors; the clinical validation report includes identification of vendors and equipment used in the clinical validation of the product. This data is summarized in the product labeling, and can be found in the Clinical User Instructions for Use. HeartFlow FFR_{CT} analyses are performed on previously physician-acquired image data and are unrelated to acquisition equipment and clinical workstations.

5.5 Intended Use

HeartFlow FFR_{CT} is a coronary physiologic simulation software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for clinically stable symptomatic patients with coronary artery disease. It provides $FFR_{CT,}$ a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. FFR_{CT} analysis is intended to support the functional evaluation of coronary artery disease.

The results of this analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow FFR_{CT} 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 judgment.

5.5.1 Warnings and Precautions

There are no new or modified warnings and precautions based on the content of this submission whose purpose is to redefinine the product boundary.

5.6 Technological Characteristics of Device

The HeartFlow FFR_{CT} device is a software medical device that allows for the quantitative and qualitative analysis of Coronary Computed Tomography Angiography (cCTA). This product has the same technological characteristics as the FFR_{CT} product submitted and cleared per K161772.

5.7 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 device performance.

Software and medical device design validation was completed and reviewed as part of the predicate review (K161772). The results concluded the device was acceptable for use. **The study conclusions are not effected by the changes proposed under this 510(k). No additional pre-clinical or clinical data is being provided with this submission.**