



August 15, 2019

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

Re: K190925

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  
Dated: April 8, 2019  
Received: April 9, 2019

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning  
Acting 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

## Indications for Use

510(k) Number (if known)

K190925

Device Name

HeartFlow Analysis

Indications for Use (Describe)

HeartFlow Analysis 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 FFRCT, 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. FFRCT 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 FFRCT 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.

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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## 5.0 510(K) SUMMARY

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

### 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](mailto:whary@heartflow.com)

Date Prepared: June 21, 2019

### 5.2 Device Identification

|                      |   |
|----------------------|---|
| Device Name:         | HeartFlow Analysis                              |
| Common Name:         | FFR <sub>CT</sub>                               |
| Classification Name: | Coronary Physiologic Simulation Software Device |
| Product Code:        | PJA   |
| Product Class:       | Class II (21 CFR 870.1415)                      |

### 5.3 Predicates

HeartFlow FFR<sub>CT</sub> v2.18 (K182035) is the identified predicate for this submission.  
This is discussed further in *VOL\_002 SEC 013 Substantial Equivalence*.  
This predicate has not been subject to a design-related recall.

### 5.4 Device Description

The HeartFlow Analysis is a coronary physiological 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 (diagnosis and treatment planning) of coronary artery disease.

HeartFlow FFR<sub>CT</sub> analyses are performed on previously physician-acquired image data and are unrelated to acquisition equipment and clinical workstations.

The new planner feature is also software, and uses as input the anatomic FFR<sub>CT</sub> model, and an idealized model generated from the FFR<sub>CT</sub> model. Just as a CFD solution is run on the anatomic FFR<sub>CT</sub> model to get the color-coded FFR<sub>CT</sub> Analysis, the planner feature runs a reduced order CFD solution for user selected combinations of the anatomic FFR<sub>CT</sub> model and the idealized model.

|  |  |  |
|--|--|--|
| HeartFlow, Inc.<br>1400 Seaport Blvd., Bldg B<br>Redwood City, CA 94063<br>T +1 (650) 241-1221<br><a href="http://www.heartflow.com">www.heartflow.com</a> |  | FFR <sub>CT</sub> v 2.Planner<br>510(k) Submission<br>2019 |
|--|--|--|

### 5.5 Intended Use

The HeartFlow Analysis is a coronary physiological 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 simulate 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.

### 5.6 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).

| Technological Characteristic  | K182035 | V2.Planner |
|---|---------|------------|
| Anatomic model generated through automatic/manual process                       | X       | X          |
| Idealized model generated from the anatomic model                               |         | X          |
| Anatomic model and Idealized model solved using CFD solver                      | X       | X          |
| Variations of Anatomic and Idealized model combinations solved using CFD solver |         | X          |

### 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.

Software testing for Planner included testing of various  $FFR_{CT}$  model modifications to represent a variety of vessel and lesion morphologies and their idealized state, and ensuring through the design verification test (DVT) that for a given modified anatomy (combinations of anatomic and idealized model) the  $FFR_{CT}$  results achieved with the Delta-solver were equivalent to those achieved with the  $FFR_{CT}$  solver.

Summaries of pre-clinical studies were reviewed as part of a prior predicate review (K161772, the predicate to K182035). The results concluded the device was acceptable for use. **The applicability of the clinical data is not effected by the changes proposed under the predicate K182035 nor this 510(k). No additional pre-clinical or clinical data is being provided with this submission.**

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

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|---|--|---|
| HeartFlow, Inc.<br>1400 Seaport Blvd., Bldg B<br>Redwood City, CA 94063<br>T +1 (650) 241-1221<br>www.heartflow.com |  | $FFR_{CT}$ v 2.Planner<br>510(k) Submission<br>2019 |
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