January 8, 2021

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

Re: K203329
 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: November 10, 2020
 Received: November 12, 2020

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 LT 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)*
K203329

Device Name
HeartFlow Analysis

Indications for Use *(Describe)*
The 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 the calculations of 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. The HeartFlow Analysis is intended to support the functional evaluation of coronary artery disease.

The HeartFlow Analysis is provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. 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.

# 510k Summary

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.<br><br>1400 Seaport Boulevard, Building B<br><br>Redwood City, CA 94063 |
|---|---|
| Contact Person: | Windi Hary, RAC<br><br>Senior Vice President, Clinical, Quality & Regulatory Compliance<br><br>HeartFlow, Inc.<br><br>1400 Seaport Boulevard, Bldg B<br><br>Redwood City, CA 94063<br><br>T +1 (650) 241-1250<br><br>F +1 (650) 368-2564<br><br>whary@heartflow.com |
| Date Prepared: | November 10, 2020 |

## 2   Device Identification

| Device Name: | HeartFlow Analysis |
|---|---|
| Common Name: | $FFR_{CT}$ |
| Classification Name: | Coronary Physiologic Simulation Software Device |
| Product Code: | PJA |
| Product Class: | Class II (21 CFR 870.1415) |

## 3   Predicates

HeartFlow $FFR_{CT}$ v2.Planner (K190925) is the identified predicate for this submission.

## 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 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 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 the calculations of $FFR_{CT}$, 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.  The HeartFlow Analysis is intended to support the functional evaluation of coronary artery disease.

The HeartFlow Analysis is provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries.  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 predicate and this product have the same technological characteristics.

The core technology remains unchanged.  There are no differences between the subject device and the predicate(s) with respect to indications and intended use.

**Table 5-1. Predicate Device Comparison**

|  | $FFR_{CT}$ v2.Planner (predicate) | $FFR_{CT}$ v3 |
|---|---|---|
| **510(k)** | K190925 | **TBD** |
| **Manufacturer** | HeartFlow, Inc. | HeartFlow, Inc. |
| **Regulation Number** | 870.1415 | 870.1415 |
| **Regulation Name** | Coronary Physiologic Simulation Software Device | Coronary Physiologic Simulation Software Device |
| **Classification** | Class II | Class II |
| **Device Common Name** | HeartFlow $FFR_{CT}$ | HeartFlow $FFR_{CT}$ |

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|  | FFR<sub>CT</sub> v2.Planner (predicate) | FFR<sub>CT</sub> v3 |
|---|---|---|
| **Product Code** | PJA | PJA |
| **Functions** | - Extract anatomic data from digital cardiac images for the 3D display and visualization of the anatomy of patient's coronary arteries<br><br>- Compute FFR$_{CT}$ | - Extract anatomic data from digital cardiac images for the 3D display and visualization of the anatomy of patient's coronary arteries<br><br>- Compute FFR$_{CT}$ |
| **Intended use** | - Review of CT angiographic images to confirm the coronary vessels<br><br>- Semi-automated tool for extraction of anatomic data (including heart structures) for coronary physiologic simulation to aid in diagnosis of coronary artery disease,<br><br>- Centerline detection<br><br>- Provides additional data derived from coronary CT anatomy and pathology<br><br>- Provide simulated hemodynamic information | - Review of CT angiographic images to confirm the coronary vessels<br><br>- Semi-automated tool for extraction of anatomic data (including heart structures) for coronary physiologic simulation to aid in diagnosis of coronary artery disease,<br><br>- Centerline detection<br><br>- Provides additional data derived from coronary CT anatomy and pathology<br><br>- Provide simulated hemodynamic information |
| **Data source (input)** | 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 of coronary anatomy and simulated data are accessed via a device with internet connectivity |
| **Physical characteristics** | - non-invasive software package<br><br>- DICOM compatible | - non-invasive software package<br><br>- DICOM compatible |
| **Safety** | Clinician 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 | FFR<sub>CT</sub> Planner (predicate) | FFR<sub>CT</sub> v3 |
|---|---|---|
| Presentation of CT images for confirmation of extracted model | X | X |

HeartFlow®

| | | |
|---|---|---|
| Automatic extraction of anatomic data from CT images for analysis | X | X |
| Volume rendering based on centerlines | X | X |
| Automatic / Semi-automatic lumen boundary determination | X | X |
| Annotate, tag, measure and record selected views | X | X |
| View the coronary vessels | X | 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 |
| Calculate functional parameters of the heart (e.g., Fractional Flow Reserve, %myo) | X | X |
| Graphic and Text Results | X | X |

**Table 12-3. Predicate Device Solver Comparison**

| | Gen 2 Solver (predicate) | Gen3 Solver (FFR$_{CT}$ v3) |
|---|---|---|
| Total coronary baseline flow | X | X |
| Flow distribution between ostia | X | X |
| Flow distribution within ostium | X | X |

Changes to flow and distribution calculations within the Gen3 solver do not raise new questions of safety and effectiveness.

# 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 predicate of K182035 that is the predicate of K190925).  The results concluded the device was acceptable for use.

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

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# 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 device identified in section 2 above.