



U.S. FOOD & DRUG
ADMINISTRATION

March 3, 2025

Bracco Diagnostics Inc.
Elyssa Murray
Director of Global Regulatory Affairs, Medical Devices and Medical Device Combination Products
510 Carnegie Center
Princeton, New Jersey 08540-0001

Re: K243881

Trade/Device Name: HeartSee™ Cardiac P.E.T. Processing Software For Myocardial Perfusion and
Coronary Flow Reserve (CFR) Version 4
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: December 16, 2024
Received: December 18, 2024

Dear Elyssa Murray:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a large, light blue, semi-transparent 'FDA' watermark.

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K243881

Device Name

HeartSee™ Cardiac P.E.T. Processing Software
For Myocardial Perfusion and Coronary Flow Reserve (CFR)
Version 4

Indications for Use (Describe)

HeartSee™ software for cardiac positron emission tomography (PET) is indicated for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map in patients with suspected or known coronary artery disease (CAD) in order to assist clinical interpretation of PET perfusion images and quantification of their severity.

HeartSee™ is intended for use by trained professionals, such as nuclear technicians, nuclear medicine or nuclear cardiology physicians, or cardiologists with appropriate training and certification. The clinician remains ultimately responsible for the final assessment and diagnosis based on standard practices, clinical judgment and interpretation of PET images or quantitative data.

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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510(K) SUMMARY

K243881

**Bracco Diagnostics Inc.
HeartSee Cardiac P.E.T. Processing Software****1. SUBMITTER/510(K) HOLDER*****Headquarters***

Bracco Diagnostics Inc.
510 Carnegie Center
Princeton, NJ 08540 USA

Contact: Elyssa Murray, Director of Global Regulatory Affairs

Phone: 609-524-2854

Contact Email: elyssa.murray@diag.bracco.com

Date Prepared: December 9, 2024

2. DEVICE NAME

Proprietary Name: HeartSee Cardiac P.E.T. Processing Software

Common name: Cardiac Positron Emission Tomography (PET)

Analysis Software

Classification Name: Emission computed tomography system.

Classification Regulation: 21 CFR 892.1200 (Class II)

Product Code: KPS

3. PREDICATE DEVICE

- Optional Screen Displays For HeartSee Cardiac P.E.T. Processing Software – HeartSee version 4 (K231731)

4. DEVICE DESCRIPTION

HeartSee is a software tool for cardiac positron emission tomography (PET) for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map for facilitating the interpretation of PET perfusion images in patients with suspected or known coronary artery disease. HeartSee is intended for use by trained professionals, such as nuclear technicians, nuclear medicine or nuclear cardiology physicians, or cardiologists with appropriate training and certification.

HeartSee contains two fundamental components. First, the software imports cardiac PET images in DICOM format from PET scanners with DICOM output. These images are reoriented to cardiac axes to produce standard tomographic and topographic displays of relative uptake. Second, the software quantifies absolute rest and stress myocardial perfusion

per unit tissue (cc/min/gm), Coronary Flow Reserve (CFR) as the stress/rest perfusion ratio and the Coronary Flow Capacity combining CFR and stress perfusion, all on a pixel basis for regional and global values. HeartSee and the predicate K231731 also display stress subendocardial to subepicardial ratio and subendocardial stress to rest ratio on relative activity tomograms, and stress relative topogram maps expressed as a fraction of maximum cc/min/g, called relative stress flow (RSF). Archiving output data is supported for clinical diagnostics, quality control and research.

In addition to these established measurements of perfusion in cc/min/g, CFR and CFC, HeartSee has software for determining left ventricular ejection fraction (EF) by PET-CT using Rb-82 compared to EF.

5. INDICATIONS FOR USE

HeartSee™ software for cardiac positron emission tomography (PET) is indicated for determining regional and global absolute rest and stress myocardial perfusion in cc/min/g, Coronary Flow Reserve and their combination into the Coronary Flow Capacity (CFC) Map in patients with suspected or known coronary artery disease (CAD) in order to assist clinical interpretation of PET perfusion images and quantification of their severity.

HeartSee™ is intended for use by trained professionals, such as nuclear technicians, nuclear medicine or nuclear cardiology physicians, or cardiologists with appropriate training and certification. The clinician remains ultimately responsible for the final assessment and diagnosis based on standard practices, clinical judgment and interpretation of PET images or quantitative data.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The proposed device and K231731 have essentially the same overall design except for the software platform migration to the Windows operating system, a few minor software application updates, and the incorporation of cybersecurity enhancements. The code in the proposed software package is essentially the same as K231731 for the determination of quantitative myocardial perfusion in ml/min/g, Coronary Flow Reserve (CFR), the Coronary Flow Capacity (CFC) map, their displays, and determining left ventricular ejection fraction (EF) by PET-CT using Rb-82.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

The nonclinical testing of the predicate device, combined with the system testing and cybersecurity testing of the proposed device, is sufficient to support substantial equivalence due to the nature of the modifications implemented in the proposed device. Since the overall

design and functionality of the proposed and predicate devices is essentially identical, performance testing was targeted to verify and validate the new and updated features of the proposed device. No new types of testing were required.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was performed in support of this 510(k) Premarket Notification.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Data from the nonclinical testing, system and cybersecurity testing, demonstrated that the proposed device meets established specifications. Therefore, the device is substantially equivalent to the predicate device.