



June 12, 2018

Bracco Diagnostics Inc.
% Ms. Patrice Marchildon
Senior Director Regulatory Affairs
259 Prospect Plains Road, Building H
MONROE TOWNSHIP NJ 08831

Re: K181343

Trade/Device Name: HeartSee Cardiac P.E.T. Processing Software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: May 18, 2018
Received: May 21, 2018

Dear Ms. Marchildon:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

A handwritten signature in black ink, appearing to read "Robert Ochs", is written over a large, light blue, semi-transparent "FDA" watermark.

for

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
510(k) Number (if known) K181343	
Device Name HeartSee Cardiac P.E.T. Processing Software	
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 by 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)	
PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.	
FOR FDA USE ONLY	
Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)	
This section applies only to requirements of the Paperwork Reduction Act of 1995. *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.* The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAstaff@fda.hhs.gov *An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*	
FORM FDA 3881 (1/14) Page of PRC Publishing Services (301) 443-6740 EF	

5. 510(k) Summary

Bracco Diagnostics Inc. HeartSee Cardiac P.E.T. Processing Software (per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

Headquarters

Bracco Diagnostics Inc.
259 Prospect Plains Road
Monroe Township, NJ 08831 USA

Contact: Patrice Marchildon, Senior Director Regulatory Affairs

Contact Phone: 609-514-2284

Contact Email: Patrice.Marchildon@diag.bracco.com

Date Prepared: May 18, 2018

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

- HeartSee Cardiac P.E.T. Processing Software (K171303)

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. Archiving output data is supported for clinical diagnostics, quality control and research.

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 by 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 K171303 are software tools using identical standard, industrial computing hardware and applications. The code in the proposed software package is identical to K171303.

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

The verification and validation testing of the predicate device verification is deemed to be sufficient for the proposed device as the devices are identical with the exception of branding.

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

Since the proposed HeartSee Cardiac P.E.T. Processing Software is identical to the K171303 version, Bracco Diagnostics Inc. has concluded that the proposed HeartSee Cardiac P.E.T. Processing Software is substantially equivalent to the predicate device K171303.