McGovern Medical School
% K. Lance Gould, M.D.
Professor of Cardiovascular Medicine
6431 Fannin Street, MSB 4.256
HOUSTON TX 77030

April 12, 2021

Re: K202679
Trade/Device Name: Optional Screen Display for HeartSee Cardiac P.E.T. Processing Software - HeartSee version 3
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: February 25, 2021
Received: March 2, 2021

Dear Dr. Gould:

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,

Michael D. O'Hara For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K202679

Device Name
Optional Screen Displays For HeartSee Cardiac P.E.T. Processing Software - HeartSee version 3

Indications for Use *(Describe)*
HeartSee version 3 software for cardiac positron emission tomography (PET) is indicated for determining regional and global absolute rest and stress myocardial perfusion in ml/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 version 3 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.

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K202679

5. 510(k) Summary

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Date of preparation: September 14, 2020

Device trade name: Optional Screen Displays For HeartSee Cardiac P.E.T. Processing Software – HeartSee version 3

Common name: Cardiac Positron Emission Tomography (PET) Analysis Software

Classification names: Regulation name: Emission computed tomography system. Regulation number: 21 CFR 892.1200. Regulatory code: Class II. Product Code: KPS.

Devices claimed for equivalence: K171303 (HeartSee version 2)

Device description: HeartSee version 3 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 version 3 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 version 3 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 HeartSee version 3 software quantifies regional absolute rest and stress myocardial perfusion per unit tissue (ml/min/g), 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.

In addition to these established measurements of perfusion in ml/min/g, CFR and CFC approved by FDA for K171303, HeartSee version 3 has the following additional clinically relevant displays. For explaining uncommon patients with angina or ST depression ≥1mm during stress PET imaging in the absence of severe perfusion defects, HeartSee version 3 has the following three additional displays:

1. Stress subendocardial to subepicardial ratio on relative activity tomograms.
2. Subendocardial stress to rest ratio on relative activity tomograms
3. Stress relative topogram maps expressed as a fraction of maximum ml/min/g and called relative stress flow (RSF).

Indications for use: HeartSee version 3 software for cardiac positron emission tomography (PET) is indicated for determining regional and global absolute rest and stress myocardial perfusion in ml/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 version 3 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.

Summary of technological characteristics of your device compared to predicate device: HeartSee version 3 and its Equivalent Predicate K171303 are software tools using identical standard, industrial computing hardware and applications. The code in the software package HeartSee version 3 is identical to K171303 including determination of quantitative myocardial perfusion in cc/min/g, Coronary Flow Reserve (CFR), the Coronary Flow Capacity (CFC) map and their displays.

In HeartSee version 3 and K171303, Coronary Flow Capacity combines CFR and stress perfusion by plotting their values for each pixel on a clinically defined, objective, color coded plot of combined ranges of values that assigns a color to that pixel for the corresponding range of combined values of CFR and stress perfusion. That color-coded pixel is then back projected into its original coordinate position in the topographic map. All pixels of the LV image are correspondingly color coded for ranges of combined CFR and stress perfusion for each pixel thereby producing a single four quadrant left ventricular map of the combined CFR-stress perfusion ranges. By incorporating all the stress perfusion and CFR data into objectively color-coded ranges on a pixel basis, the CFC map accounts for regional and global biological heterogeneity, objectively simplifies complex data for optimal clinical interpretation and associates with major adverse coronary events (MACE) with decreased death or myocardial infarction after revascularization better than CFR or stress flow alone.

In addition to these established measurements of perfusion in ml/min/g, CFR and CFC approved by FDA for K171303, HeartSee version 3 has the following additional clinically relevant displays. For explaining uncommon patients with angina or ST depression ≥1mm during stress PET imaging in the absence of severe perfusion defects, HeartSee version 3 has the following three additional displays:

4. Stress subendocardial to subepicardial ratio on relative activity tomograms.
5. Subendocardial stress to rest ratio on relative activity tomograms
6. Stress relative topogram maps expressed as a fraction of maximum ml/min/g and called relative stress flow (RSF).

Summary of performance data: By Cox multivariate analysis and Kaplan-Meier plots, CFR and separately stress perfusion derived by HeartSee version 3 associate significantly with major adverse coronary events (MACE) and mortality and their reduction after revascularization. By ROC analysis and paired t-tests, the stress subendo/subepicardial ratio, the subendocardial stress/rest ratio and the relative stress flow (RSF) associate with angina or ST depression ≥1mm during stress PET in patients with only mildly reduced CFC and no severely reduced CFC.

Conclusions drawn from the performance data demonstrating that the device is as safe, as effective, and performs as well as or better than the predicate device:
HeartSee version 3 performs identically to K171303 for determining rest and stress perfusion in cc/min/g, CFR and CFC for significant associations with MACE, mortality and its reduction after revascularization. As an additional superiority over K171303, HeartSee version 3 has subendocardial and relative stress flow metrics that explain the uncommon occurrence of angina or ST depression ≥1mm in the absence of severe stress defects.