University of Texas Medical School at Houston, Texas
% K. Lance Gould, M.D.
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Re:  K171303
   Trade/Device Name:  Optional Screen Displays for HeartSee Cardiac P.E.T Processing Software
   Regulation Number:  21 CFR 892.1200
   Regulation Name:  Emission Computed Tomography System
   Regulatory Class:  Class II
   Product Code:  KPS
   Dated:  September 19, 2017
   Received:  September 20, 2017

Dear K. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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

Enclosure
Indications for Use

HeartSee K171303 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 K171303 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.

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)

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FORM FDA 3881 (1114)
5. 510(k) Summary K171303

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Date of preparation: September 19, 2017

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

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

Classification names: Regulation name: Emission computed tomography system.

Devices claimed for equivalence: K143664

Device description:
HeartSee K171303 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 K171303 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 K171303 software quantifies absolute rest and stress myocardial perfusion per unit tissue (cc/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.

Indications for use:
HeartSee K171303 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 K171303 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:** K171303 and K143664 are software tools using identical standard, industrial computing hardware and applications. The code in the software package K171303 is identical to K143664 including determination of quantitative myocardial perfusion in cc/min/g and Coronary Flow Reserve (CFR) and their displays except for the addition of the Coronary Flow Capacity (CFC) map to K171303.

In 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 global and regional heterogeneity, objectively simplifies complex data for optimal clinical interpretation and associates with major adverse coronary events (MACE) and decreased death and myocardial infarction after revascularization better than CFR or stress flow alone in K143664.

**Summary of performance data:**
In 4188 rest and 4188 stress PET perfusion scans were analyzed by K143664 and separately by K171303. Rest and stress perfusion values in cc/min/g and CFR using K171303 were identical within two decimal places to the values using K143664, as were the mean values and their standard deviations. Rest-stress perfusion and CFR using K171303 and 143664 were tightly correlated with R = 1.0 and P < 1 x 10^{-16}.

By Cox multivariate analysis, CFR and separately stress perfusion associate significantly with major adverse coronary events (MACE) equally well for K171303 and K143664. However, the CFC map of K171303 associates significantly with higher MACE than either CFR or stress perfusion alone and also associates significantly with reduced death and myocardial infarction after revascularization. In contrast, CFR and stress perfusion alone in K143663 does not have a significant association with reduced death and myocardial infarction after revascularization.

**Conclusions drawn from the performance data that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device:**
K171303 performs identically to K143664 for determining rest and stress perfusion in cc/min/g, CFR and for significant associations with MACE. However, the CFC map of K171303 performs better for risk stratification than K143664 by its association with higher MACE than CFR or stress perfusion alone in K143664. As an additional superiority for risk stratification, K171303 associates with reduced death and myocardial infarction after revascularization that is not seen for CFR or stress perfusion alone in K143664. Therefore, K171303 has the same functionality as K143664 but performs better than K143664 for risk stratification of patients with suspected or known CAD.