Cardiovascular Imaging Technologies
℅ Ms. Melanie Hasek
Associate Director, Regulatory Publishing
PRA Health Sciences
9755 Ridge Drive
LENEXA KS 66219

August 11, 2020

Re: K201933
Trade/Device Name: ImagenSPECT™ 3.0
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS, LLZ
Dated: July 9, 2020
Received: July 13, 2020

Dear Ms. Hasek:

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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201933

Device Name
ImagenSPECT™ 3.0

Indications for Use *(Describe)*
The ImagenSPECT™ 3.0 system is a software application that provides a processing environment for the analysis and display of cardiac SPECT and planar images. The results of this processing may be used in determining the presence of cardiac diseases. Data for ImagenSPECT 3.0 is derived from a nuclear medicine gamma camera. The resulting datasets may be either planar or 3D tomograms of patient anatomy. This software can also be used for processing display and quantitation of multigated acquisition blood pool scans (MUGA) specifically the left ventricular ejection fraction (LVEF). ImagenSPECT™ 3.0 can also be used for quantitation of planar and SPECT, early and late 99mTc pyrophosphate images.

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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6. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92.

General Information:

A. Submitted By: Cardiovascular Imaging Technologies
4320 Wornall Road, Suite 114
Kansas City, MO 64111
Tel: 816-531-2842
Fax: 816-531-0643

Contact Person: James A. Case

Date Prepared: July 10, 2020

B. Device Trade Name: ImagenSPECT™ 3.0

Classification Name: System, Emission Computed Tomography
21 CFR 892.1200 (KPS),
Class II
System, Image Processing, Radiological
21 CFR 892.2050 (LLZ)
Class II

C. Predicate Devices: Cardiovascular Imaging Technologies ImagenSPECT (k152503)
Siemens e.Cam Computer/e.Soft Workstation (k023190)

D. Device Description:

ImagenSPECT™ 3.0 is a Windows application which allows physicians and healthcare professionals to inspect, reconstruct and reorient myocardial perfusion SPECT images. The system processes gated and ungated SPECT cardiac images to create 3D tomographic data. The user can correct for patient motion, change filter settings, change reconstruction settings, range of reconstruction, and reorientation angles. The application also models the influence of distance dependent blur. The use of this system is limited to qualified, licensed healthcare providers (radiologists, nuclear cardiologists or nuclear medicine physicians) trained in the use of nuclear medicine imaging devices.

This software also processes, display and performs quantitative calculations of LVEF on multigated acquisition blood pool scans (MUGA). ImagenSPECT™ 3.0

is used to quantitate the uptake of ^{99m}Tc pyrophosphate in early and late planar and SPECT studies.

The ImagenSPECT™ 3.0 system is designed to take nuclear medicine data from commercially available SPECT systems and process the data into a format that can be visualized by a separate computer program or workstation.

In addition, quarter-counts, half dose and/or half-time scans can be reconstructed with ImagenSPECT™ 3.0 using resolution recovery, iterative reconstruction and is equivalent to the predicate ImagenSPECT™ (k152503) using half-counts and full counts (full-time scan, half dose/ half-time, full dose).

E. Indications for Use:

The ImagenSPECT™ 3.0 system is a software application that provides a processing environment for the analysis and display of cardiac SPECT and planar images. The results of this processing may be used in determining the presence of cardiac diseases. Data for ImagenSPECT™ 3.0 is derived from a nuclear medicine gamma camera. The resulting datasets may be either planar or 3D tomograms of patient anatomy. This software can also be used for processing display and quantitation of multigated acquisition blood pool scans (MUGA) specifically the left ventricular ejection fraction (LVEF). ImagenSPECT™ 3.0 can also be used for quantitation of planar and SPECT, early and late ^{99m}Tc pyrophosphate images.

F. Comparison of Technical Characteristics to Predicate Device:

The ImagenSPECT™ 3.0 system and its predicates, the ImagenSPECT™ (k152503) and the e.Cam/e.Soft™ system use the same type of data sets for analysis and calculation of data.

G. Device performance, verification and validation

ImagenSPECT™ 3.0 was tested in phantom and patient data to verify the successful performance of additional features. Specifically, this includes the quantitative assessment of LVEF on multigated acquisition blood pool scans (MUGA), quantitative uptake of ^{99m}Tc pyrophosphate and one quarter time myocardial perfusion SPECT testing.

^{99m}Tc pyrophosphate heart contralateral ratios from ImagenSPECT 3.0 was compared with heart contralateral ratios from the Siemens e.soft system. The Pearson rorrelation coefficient (r) between ImagenSPECT 3.0 and Siemens e.soft was 0.96 and the p value for student paired t-test was 0.15.

Quantitative measurements of MUGA derived LVEF using ImagenSPECT 3.0 were correlated with LVEF measurements determined using the Siemens e.soft system (r=0.92) and were not statistically different (p=0.13).

One quarter time myocardial perfusion SPECT testing was examined in both phantom and patient studies. Phantom studies demonstrated that a change in signal-to-noise ratio 98.9% of the signal-to-noise using one quarter time reconstructed using ImagenSPECT 3.0 when compared to full-time unfiltered reconstructed perfusion images. One quarter time patient studies reconstructed using ImagenSPECT 3.0 were compared with conventional ordered subsets expectation maximization (OSEM) reconstructions. Myocardial perfusion SPECT images were analyzed using a 17 segment polar map of tracer uptake. The average segmental difference between full-time OSEM and one quarter time ImagenSPECT 3.0 was 5.9% and the P value of the paired t-test was 0.76.

In addition to testing ImagenSPECT 3.0 clinical performance, ImagenSPECT 3.0 was also successfully tested for the success of risk mitigation strategies.

H. Summary:

Testing and comparison of technological characteristics and intended uses found that all components of the ImagenSPECT™ 3.0 system are equivalent to the predicates. In addition, quarter-counts, e.g. half dose and/or half-time, reconstructed with ImagenSPECT™ 3.0 using resolution recovery, iterative reconstruction was equivalent to the predicate ImagenSPECT™ (k152503) using half-counts and full counts (full-time scan, half dose/ half-time, full dose).