



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Cardiovascular Imaging Technologies
% Ms. Melanie Hasek
Manager, Regulatory Publishing
PRA Health Sciences
9755 Ridge Drive
LENEXA KS 66219

January 25, 2016

Re: K152503
Trade/Device Name: ImagenSPECT™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, LLZ
Dated: January 7, 2016
Received: January 8, 2016

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. 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 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 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 yours,



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

SEE UPDATED PDF FORM

510(k) Number (if known): K152503

Device Name: ImagenSPECT™

Indications For Use:

The ImagenSPECT™ system is a software application that provides a processing environment for the analysis and display of cardiac SPECT images. The results of this processing may be used in determining the presence of cardiac diseases. Data for ImagenSPECT is derived from a nuclear medicine gamma camera. The resulting datasets may be either planar or 3D tomograms of patient anatomy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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 55
Kansas City, MO 64111
Tel: 816-531-2842
Fax: 816-531-0643
- Contact Person: James A. Case
- Date Prepared: September 1, 2015
- B. Device Trade Name: ImagenSPECT™
- Classification Name: System, Emission Computed Tomography
21 CFR 892.1200 (KPS)
System, Image Processing, Radiological
21 CFR 892.2050 (LLZ)
- C. Predicate Devices: ADAC JETStream (k061029)
Siemens e.Cam Computer/e.Soft Workstation
(k023190)
Philips AutoSPECT with Astonish (k090403)
- D. Device Description:

ImagenSPECT™ 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 setting, 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.

The ImagenSPECT™ 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.

E. Indications for Use:

The ImagenSPECT™ system is a software application that provides a processing environment for the analysis and display of cardiac SPECT images. The results of this processing may be used in determining the presence of cardiac diseases. Data for ImagenSPECT is derived from a nuclear medicine gamma camera. The resulting datasets may be either planar or 3D tomograms of patient anatomy.

F. Comparison of Technical Characteristics to Predicate Device:

The ImagenSPECT™ system and its predicates, the e.Cam/e.Soft™ system, the JETStream™ and Astonish™ utilize the same type of data sets for analysis and calculation of data.

H. Summary:

Testing and comparison of technological characteristics and intended uses found that all components of the ImagenSPECT™ system are equivalent to the predicates. In addition, half-count density (full-time scan, half dose/ half-time, full dose), reconstructed with ImagenSPECT using resolution recovery, iterative reconstruction was equivalent to the predicate with the same claim (AutoSPECT with Astonish, k090403).