K122241

OCT 2 4 2012

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
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Contact Person: James A. Case

Date Prepared: July 20, 2012

B. Device Trade Name: Imagen3D™

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

C. Predicate Devices: ECAT LSO PET/CT 16
ImagenPRO®

D. Device Description:

Imagen3D™ is a Windows application that works in conjunction with ImagenPRO® as an additional processing step for data acquired in 3D (septa retracted mode). Because of the increase count rate of PET scanners in 3D mode, a lower dosage of the radiopharmaceutical is recommended to avoid dead time issues with the scanners. The resulting 3D sinograms can then be processed in ImagenPRO® to produce 3D tomograms. 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 Imagen3D™ system is designed to take Fourier rebinned sinogram data from commercially available dedicated PET and PET/CT systems acquired in 3D (septa retracted) and scatter correct the data for export into ImagenPRO® for tomographic processing.

E. Indications for Use:

The Imagen3D™ system is software application that works in conjunction with ImagenPRO® to correct lower dosage, PET 3D data for photon scatter. The resulting 3D datasets can be reconstructed using ImagenPRO® to produce PET and/or PET/CT reconstructed tomograms.

F. Comparison of Technical Characteristics to Predicate Device:

The Imagen3D™ system and its predicates, the ECAT LSO PET/CT 16 and the ImagenPRO® 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 Imagen3D™ system are equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 24 2012

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

Re: K122241
Trade/Device Name: Imagen3D™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: July 20, 2012
Received: July 27, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122241

Device Name: Imagen3D™

Indications For Use:

The Imagen3D™ system is software application that works in conjunction with ImagenPRO® to correct for photon scatter and prompt gamma contamination present in PET 3D data. The resulting 3D datasets can be reconstructed using ImagenPRO® to produce PET and/or PET/CT reconstructed tomograms.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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