K050366

MAR 17 2005

VII. 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

B. Device Trade Name: ImagenPRO™

Classification Name: System, Emission Computed Tomography

C. Predicate Devices: Siemens/CTI Accel -- CPS Innovations - K002584
GE Discovery LS – General Electric - K023988

D. Device Description:

ImagenPRO™ is a software application installed on desktop computers which allows physicians and healthcare professionals to inspect, reconstruct and reorient myocardial perfusion PET images. The system processes perfusion and gated PET raw emission and transmission data to create 3D tomographic data. The user can select correction parameters, filter setting, range of reconstruction, and reorientation angles. 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.

E. Indications for Use:

The ImagenPRO™ system is a software and/or computer system that allows the user to visualize raw PET and/or PET/CT data, reconstruct myocardial perfusion PET or PET/CT images and reorient PET and/or PET/CT reconstructed tomograms.

F. Comparison of Technical Characteristics to Predicate Device:

The ImagenPRO™ system and its predicates, the Siemens e.cat and the GE Discovery LS 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 ImagenPRO™ system are equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2005

Cardiovascular Imaging Technologies
% Ms. Melanie Hasek
Sr. Regulatory Affairs Specialist
Regulatory/Clinical Consultants, Inc.
200 NE Mulberry
LEE'S SUMMIT MO 64086

Re: K050366
Trade/Device Name: ImagenPRO™ System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: KPS and LLZ
Dated: February 14, 2005
Received: February 14, 2005

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

I. Indications for Use:

Indications for Use Form

510(k) Number (if known): K050366

Device Name: ImagenPRO™

Indications For Use:

The ImagenPRO™ system is software that allows the user to visualize raw PET and/or PET/CT data, reconstruct myocardial perfusion PET or PET/CT images and reorient PET and/or PET/CT reconstructed tomograms.

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050366da