MAR 3 1 2009

K090403

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. SUBMITTED BY

Philips Medical Systems (Cleveland), Inc.
3860 N. First Street
San Jose, CA 94135

Contact Person:
Robert Z. Phillips
Tel: 440-483-2100
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B. DEVICE TRADE NAME

Trade Name:	AutoSPECT®
Common Name:	Gamma Camera Systems

C. CLASSIFICATION(S) OF THE DEVICE

Classification Name:	Emission Computed Tomography System, (21CFR 892.1200)
Classification Panel:	Radiology
Device Class:	21CFR 892.1200, Class II
Product Code:	90 KPS
Regulation Number:	21 CFR 892.1200

D. DATE PREPARED

Date:	14 February 2009

E. PREDICATE DEVICE(S)

Manufacturer	Product Name	510(k) No.
Philips Medical Systems (Cleveland), Inc. (formerly ADAC Laboratories)	AutoSPECT®	K042903
Digirad Corporation (claim refernce)	Cardius-1, -2, -3 and Cardius 1, 2, 3, XPO, 2020TC (with nSpeed)	K082368

F. INTENDED USE

AutoSPECT® produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient. This software is intended to provide enhancements to gamma camera emission image processing by automating previously manual image processing functions, providing manual and automated motion correction, providing enhanced reconstruction algorithms that include resolution recovery, scatter correction, noise compensation, and attenuation correction via application of a transmission dataset.

NOTE: This submission is for an expansion of marketing claims and thus the intended use of this device is identical to that of the predicate device (AutoSPECT®).

G. DEVICE DESCRIPTION

AutoSPECT® is a software application that produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient via automatic or manual processing. One or more cardiac SPECT, gated SPECT, or MCD cardiac data sets may be processed automatically using AutoSPECT®. Additionally, one or more non-cardiac SPECT, gated SPECT, or MCD data sets may be processed manually. AutoSPECT® contains basic data-processing algorithms that have been cleared previously; in addition to enhanced data reconstruction algorithms that include scatter correction, resolution recovery, map-based attenuation correction, and OSEM (Astonish SPECT) reconstruction.

The AutoSPECT® software option may be used on images from a gamma camera system that are DICOM 3.0 compatible. The following data sets may be used:

- Cardiac, brain, or other (bone, liver, etc.) SPECT datasets

- Gated SPECT datasets
- Vantage SPECT datasets
- SPECT-CT datasets
- Total Body SPECT datasets
- MCD and MCD-AC datasets

AutoSPECT® provides the user three options for automatically processing cardiac datasets: AutoAll, Auto Recon, and Auto Reorient. Each option is described in greater detail in the Software Description section, Section 4.

AutoSPECT® also allows the user to process non-cardiac SPECT and MCD datasets. In this case, the operator manually positions the reconstruction limit lines to reconstruct transverse data sets. If necessary, the data set can be reoriented manually by positioning the azimuth, elevation, and twist lines to the desired locations.

In addition, the capability of processing groups of SPECT data sets in a batch mode fashion is provided. Once the operator has selected the datasets and determined the processing method, AutoSPECT® processes the first dataset, followed by all remaining datasets without further interaction from the user.

AutoSPECT® application runs on Microsoft Windows XP Professional environment. The minimum hardware requirements are listed:

- Intel x86/Pentium class processor > 1 GHz ;
- Graphics capability must meet or exceed 1280x1024 pixels with 32 bit pixel depth;
- 30 GB of disk space (minimum);
- 512 MB of DRAM (minimum);
- 10/100 BaseTX Ethernet interface;
- Port capable of supporting a dongle;
- CD drive- capable of reading and writing;
- 56 Kbps modem (minimum)

H. TECHNOLOGICAL COMPARISON (DESCRIPTION OF CHANGES)

AutoSPECT® (claim extension) and the predicate (AutoSPECT®), have identical indications for use and use the same methods for motion correction, reconstruction, and display of images. AutoSPECT® (claim extension) like the predicate device also has the tools for automated and manual processing of images. AutoSPECT® (claim extension) provides the same enhanced data reconstruction algorithms that include scatter correction, resolution recovery, map-based attenuation correction, and OSEM (Astonish) reconstruction as the predicate. The purpose of this submission is to support the expansion of claims relative to half-count imaging (using Astonish & Astonish -AC). The functionality to support these claims has already been cleared, but not highlighted given that the present supporting data had not yet been obtained.

I. CONCLUSION

AutoSPECT® (claim extension) is substantially equivalent to the predicate device, AutoSPECT®, based on an identical intended use and technology. Additionally, analysis was performed (provided in Section 3) on previously scanned images via multi-center evaluations utilizing data from 297 patient images acquired using Philips' imaging systems and AutoSPECT® (with Astonish & Astonish AC). These studies concluded that count data processed with the previously cleared reconstruction technique, Astonish (previously cleared in AutoSPECT®), at half count density (e.g., full-time scan, half dose / half-time scan, full dose), produced equivalent diagnostic accuracy (equivalent sensitivity, specificity, and normalcy), better image quality for perfusion imaging, and improved equivalent interpretive certainty versus full-time back projection. Additionally, these studies concluded that count data processed with Astonish-AC (Astonish + Attenuation Correction) produced improved diagnostic accuracy (improved specificity and normalcy) versus full-time back projection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 1 2009

Philips Medical Systems (Cleveland), Inc.
% Mr. Robert Z. Phillips
Sr. Dir. Quality, Regulatory, and Sustainability
Philips Medical Systems
595 Miner Road
CLEVELAND OH 44143

Re: K090403
Trade/Device Name: AutoSPECT®
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: February 14, 2009
Received: February 17, 2009

Dear Mr. Phillips:

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 (PMA), 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 os 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.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): **K090403**

Device Name: **AutoSPECT®**

Indications for Use:

AutoSPECT® produces images, which depict the three-dimensional distribution of radiopharmaceutical tracers in a patient. This software is intended to provide enhancements to gamma camera emission image processing by automating previously manual image processing functions, providing manual and automated motion correction, providing enhanced reconstruction algorithms that include resolution recovery, scatter correction, noise compensation, and attenuation correction via application of a transmission dataset.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090403