K081135

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

APR 2 9 2008

General Information

A. ***Submitter/ Contact Person***:

Philips Medical Systems (Cleveland), Inc.
595 Miner Rd.
Cleveland, OH 44143

Melinda Novatny
Tel: (440) 483-4255
Fax: (440) 483-2300

B. ***Device Trade Name***: GEMINI Condor

Common Name: Positron Emission Tomography
Computed Tomography X-Ray

Classification Name: System, Emission Computed Tomography, (892.1200)
System, Computed Tomography X-Ray, (892.1750)

Device Class: 21CFR 892.1200, Class II
21 CFR 892.1750, Class II

Product Code: 90 KPS and 90 JAK

Classification Panel: Radiology

C. ***Date prepared***: March 17, 2008

D. ***Predicate Device***:

GEMINI Raptor System (GEMINI TF)	(K052640)
AcQSim Multislice CT Scanner (Brilliance CT Big Bore)	(K033357)

E. ***Performance Standards:***

- 21 CFR 1020.30 - 1020.33 Performance Standards for Ionizing Radiation Emitting Products, Computed Tomography Equipment (Applicable Sections)
- NEMA NU-2

F. ***Intended Use***:

The device is a diagnostic imaging system for fixed or mobile installations that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The CT subsystem produces cross-sectional images of the body by computer reconstruction of x-ray transmission data. The PET subsystem produces images of the distribution of PET radiopharmaceuticals in the patient body (specific radiopharmaceuticals are used for whole body, brain, heart and other organ imaging). Attenuation correction is accomplished by CTAC. The device also provides for list mode, dynamic, and gated acquisitions.

Image processing and display workstations provide software applications to process, analyze, display, quantify and interpret medical images/data. The PET and CT images may be registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined metabolic and anatomical data at different angles. Trained professionals use the images in:

- The evaluation, detection and diagnosis of lesions, disease and organ function such as but not limited to cancer, cardiovascular disease, and neurological disorders.
- The detection, localization, and staging of tumors and diagnosing cancer patients.
- Treatment planning and interventional radiology procedures.

The device includes software that provides a quantified analysis of with regional cerebral activity from PET images.

Cardiac imaging software provides functionality for the quantification of cardiology images and datasets including but not limited to myocardial perfusion for the display of wall motion and quantification of left-ventricular function parameters from gated myocardial perfusion studies and for the 3D alignment of coronary artery images from CT coronary angiography onto the myocardium.

Both subsystems (PET and CT) can also be operated independently as fully functional, diagnostic imaging systems including application of the CT scanner as a radiation therapy simulation scanner.

G. ***Device Description/ Comparison with Predicate Device***:

The device is a hybrid diagnostic imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) scanners that can be utilized in fixed installations or mobile environments. The device is comprised of the following system components/subsystems: Positron Emission Tomography (PET), X-ray Computed Tomography (CT), a patient table, gantry separation unit, and the acquisition and processing workstations.

H. ***System Performance Test/ Summary of Studies***:

To minimize electrical, mechanical and radiation hazards, Philips Medical System adheres to recognized and established industry practice. Radiation safety is assured by compliance and certification to the performance standards for ionizing radiation emitting product, 21CFR 1020.30 and 21CFR 1020.33. The radiation safety product report will be filed in accordance with 21CFR 1002.10 with the Center for Device and Radiological Health. Electrical and mechanical safety is assured by adherence and certification to the applicable standards in the IEC 60601-1 series. The device performance was measured in accordance with the NEMA-NU2 standard.

I. ***Comparison to Predicate Devices:***

The basic differences in the system include the following:

- Different CT subsystem
- Modifications to the patient table

In conclusion, the device is substantially equivalent to the predicate devices based upon similar intended use, technological comparison, and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2008

Philips Medical Systems (Cleveland), Inc.
% Mr. Morten Christensen
Staff Engineer
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K081135
Trade/Device Name: GEMINI Condor
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: April 16, 2008
Received: April 21, 2008

Dear Mr. Christensen:

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (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 Manufacturers, 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/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

Indications for Use

510(k) Number (if known): ~~Not Known~~ K 081135

Device Name: GEMINI Condor

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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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081135