K032036 JUL 11 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information

A. Submitter/ Contact Person:

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

Christof Littwitz
Tel: (440) 483-3585
Fax: (732) 352-6897

B. Device Trade Name: Gemini 16

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

C. Date prepared: June 20, 2003

D. Predicate Device: Gemini (K013521)
Mx8000 IDT (K012009)

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 an imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT). The device produces attenuation and non-attenuation corrected images of the distribution of PET radiopharmaceuticals in the head, body and total body as well as x-ray transmission images of these areas. The PET and CT images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined PET and anatomical data at different angles for interpretation by trained health professionals. The PET and CT portions of the system can be used either as an integrated system or as a stand-alone PET or CT system. The device can provide CT data suitable for use in attenuation correction.

G. Device Description/ Comparison with Predicate Device:

The device is a combination Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) scanner that can be utilized in both conventional, fixed installations or mobile environments. The system integrates the two system operator consoles into a single workstation to allow straightforward planning and system operation. The individual PET and the CT gantries remain intact as major subsystem located within a common integrated housing. It can be used in clinical protocols and procedures, which have been clinically conducted in a separate CT system and/or a PET system.

The system is intended for use primarily as a clinical whole body oncology scanner with high-end multislice CT capability and high-end GSO based PET performance. It mechanically separates to allow for the greater flexibility for above three operation modes.

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 NEMA-NU2 standard.

I. Comparison to Predicate Device

The device is a modification of the currently marketed Gemini PET/CT System (K013521) with design modifications resulting in decreasing patient scan time and improvement in attenuation correction speed. The similarities and differences between the Gemini 16 and the predicate devices are described in detail in Section VI of the premarket notification.

In conclusion, the device is substantially equivalent to the predicate device Gemini (K013521) and the Mx8000IDT (K012009) systems 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

JUL 11 2003

Philips Medical System, Inc.
% Mr. Heinz Joerg Steneberg
Primary Third Party Reviewer
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K032036
Trade/Device Name: Gemini 16
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: June 27, 2003
Received: July 1, 2003

Dear Mr. Steneberg:
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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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 STATEMENT

510 (k) NUMBER (IF KNOWN): K032036

DEVICE NAME: GEMINI 16

INDICATIONS FOR USE:

The device is an imaging system that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT). The device produces attenuation and non-attenuation corrected images of the distribution of PET radiopharmaceuticals in the head, body and total body as well as x-ray transmission images of these areas. The PET and CT images are registered and displayed in a "fused" (overlaid in the same spatial orientation) format to provide combined PET and anatomical data at different angles for interpretation by trained health professionals. The PET and CT portions of the system can be used either as an integrated system or as a stand-alone PET or CT system. The device can provide CT data suitable for use in attenuation correction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David B. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032036