K03 3326

OCT 2 9 2003

# Philips Medical Systems Inc.
# 510(k) Summary

# "Philips Plus" CT Scanner

## 1. Submitter

Philips Medical Systems (Cleveland), Inc.
595 Miner Road
Cleveland, OH 44143
(440) 483-3000

**Contact:**
Robert L. Turocy
Philips Medical Systems
595 Miner Road
Cleveland, OH 44143
Telephone: 440 483 3528
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**Date of Summary:** June 19, 2001

## 2. Device Name and Classification

**Device Name:** "Philips Plus" CT Scanner

**Classification Name:** Computed Tomography X-Ray System

The FDA has classified the Computed Tomography X-Ray System as Class II in 21 CFR 892.1750 (Product Code 90JAK)

## 3. Device Description

The "Philips Plus" is a Whole Body Computed Tomography X-Ray System featuring a continuously rotating X-ray tube and detectors gantry and multi-slice capability of up to 40 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body taken at different angles and planes. This device also includes signal analysis and display equipment, patient and equipment supports, components and accessories.

## 4. Intended Use Of The Device

The "Philips Plus" is a Whole Body Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes.

## 5. Comparison to Predicate Devices

In the opinion of Philips Medical Systems Inc., the "Philips Plus" CT scanner is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely:

- Mx8000 IDT, K012009
- Mx8000 v5.0, K010817

## 6. Safety and Effectiveness Considerations

The safety of the device is assured by adherence to GMP practices and to International Standards. Potential hazards are identified in a hazard analysis and controlled in the following manner:
**Software** safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures were adhered to, and test results demonstrate that the option specifications and functional requirements were met.
**Electrical and Mechanical** safety is assured by adherence to IEC 60601-1 standards.
**Radiation** safety is assured by compliance with 21 CFR, Subchapter J performance standards.

## 7. Substantial Equivalency Statement

Based on the above considerations, it is Philips's opinion that the **"Philips Plus"** CT scanner is substantially equivalent in safety and effectiveness to the predicate devices, Mx8000 IDT, K012009 and Mx8000 v5.0, K010817.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Philips Medical Systems
% Mr. Juergen Welte
Program Manager, Third Party
Review Program
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K033326
Trade/Device Name: "Philips Plus" Computed Tomography System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: October 14, 2003
Received: October 16, 2003

Dear Mr. Welte:

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

510(k) Number (if known): K033326 Page 1 of 1

Device Name: "Philips Plus"

**Indications for Use:** The "Philips Plus" is a Computed Tomography X-Ray System intended to produce images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033326