DEC 17 2008

K083498

510(k) Summary
Philips Medical Systems (Cleveland) Inc.
"Brilliance Volume"

This summary of this 510(k) provides safety and effectiveness information submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter

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

Contact:

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Date of Summary: September 1, 2008

2. Device Name and Classification

Device Name: Philips MX 16 slice
Classification Name: Computed Tomography X-Ray System

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

3. Predicate Device Information

In the opinion of Philips Medical Systems Inc., the "Philips MX 16 slice" CT scanner is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely: the Brilliance CT 16-slice in K012009 (a.k.a. MX8000 IDT CT Scanner).

4. Device Description

The "Philips MX 16 slice" is a Whole Body Computed Tomography X-Ray System featuring a continuously rotating X-ray tube and detectors gantry and multi-slice capability. 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.

5. Intended Use of the device

The Philips MX 16-slice CT system can be used as a Whole Body Computed Tomography X-ray System featuring a continuously rotating x-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.

6. Comparison to Predicate Devices

In the opinion of Philips Medical Systems (Cleveland), Inc., the "Philips MX 16 slice" CT scanner is of comparable type and substantially equivalent to the legally marketed devices because it has the similar technological characteristics and sub-assemblies as the current commercial distribution of Brilliance CT 16-slice (K012009).

The safety and effectiveness of the "Philips MX 16 slice" is assured by adherence to Good Manufacturing Practices (GMP) 21 CFR 820 and to International Standards ISO 13485:2003. 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 are adhered to, and meeting the specifications and functional requirements is demonstrated via testing.

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.

Based on the above considerations, it is Philips's opinion that the **"Philips MX 16 slice"** CT scanner is substantially equivalent in safety and effectiveness to the predicate device: Brilliance CT 16-slice with 510(k) Number K012009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Philips Medical Systems (Cleveland), Inc.
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K083498
Trade/Device Name: Philips MX 16 Slice CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Conry:

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 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 894.xxx	(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 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 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,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Device Name: **Philips MX 16-slice CT system**

Indications for Use:

The Philips MX 16-slice CT system can be used as a Head and Whole Body Computed Tomography X-ray System featuring a continuously rotating x-ray tube and detector array with multislice capability up to 16 slices simultaneously. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.

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 K083498