

510(k) Summary
Philips Medical Systems (Cleveland) Inc.
Brilliance Dual Energy option

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
Cleveland, OH 44143
(440) 483-3000

JUN 23 2009

Contact:

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Date of Summary: January 7, 2009

2. Device Name and Classification

Device Name: Brilliance Dual Energy option
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 Brilliance Dual Energy option is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely: the Philips Brilliance Volume – K060937 and the GE Lightspeed CT750 HD – K081105.

4. Device Description

Philips Healthcare offers a Dual Energy scanning option on the Brilliance CT Scanner. The Brilliance Dual Energy option automates the execution of sequential scanning protocols acquired during the same episode of care using two unique tube voltages and/or currents. The acquired datasets can be displayed side-by-side or overlaid and then analyzed to augment the review of anatomical and pathological structures. Dual energy imaging, by nature of differing x-ray energy values, enables the identification of attenuation differences found in those structures between the two applied energies.

5. Intended Use of the device

The Brilliance CT is a 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. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

The dual energy option allows the system to acquire two CT images of the same anatomical location using two distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the doses of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies. This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials.

6. Comparison to Predicate Devices

In the opinion of Philips Medical Systems (Cleveland), Inc., the Brilliance CT scanner with Dual Energy option 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 Philips Brilliance Volume (K060937) and the GE Lightspeed CT750 HD (K081105).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2009

Michael Chilbert, Ph.D., P.E.
Quality & Regulatory Engineer
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K090462

Trade/Device Name: Brilliance Dual Energy option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 5, 2009
Received: June 9, 2009

Dear Dr. Chilbert:

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.

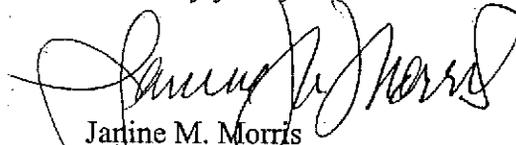
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in black ink, appearing to read "Jarine M. Morris". The signature is fluid and cursive, with a large initial "J" and "M".

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

Enclosure

510(k) Number (if known): K090462

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Device Name: Brilliance Dual Energy option

Indications for Use: The Brilliance CT is a 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. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

The dual energy option allows the system to acquire two CT images of the same anatomical location using two distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the doses of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies. This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials.

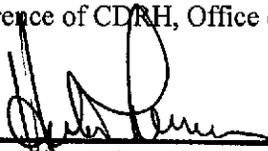
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K090462