K092747

510(k) Summary
Philips Medical Systems (Cleveland) Inc.
Philips' Comprehensive Cardiac Analysis (CCA)
Plaque Assessment Tool

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

1. Submitter

OCT - 9 2009

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

Contact:
Michael A. Chilbert, Ph.D., P.E.
Telephone: 440 483 3284
FAX: 440 483 4918
Email: Michael.chilbert@philips.com

Date of Summary: March 1, 2009

2. Device Name and Classification

Device Name:	Philips' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool
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' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely:

- Philips Medical Systems (Cleveland), Inc., Brilliance CT, Private Practice CV Configuration, K042293
- Shina Systems Ltd., CardioCT, K070226
- GE- CardIQ Fusion, K061370
- GE - Advanced Vessel Analysis LI, K060779
- Vital Imaging - Vitrea2 Ver. 3.9, K061624 (specifically the SUREPlaque tools)
- Siemens – *syngo* Circulation, K063762

4. Device Description

The Plaque Analysis option was added to the Comprehensive Cardiac Analysis option (a.k.a. CCA) predicate device. It provides analysis of the vessel lumen and wall and makes it easier to detect findings in the coronary vessels.
The Plaque Analysis application calculates lumen and vessels contours, detects findings along the vessel wall by a single click algorithm and provides a set of measurements for all the detected findings. The option includes visualization and manual correction tools.

Outputs of the application include coronary findings segmentation and quantification.

5. Indications for Use of the device

The Plaque Analysis option is a non-invasive diagnostic reading software intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques.

6. Intended Use of the device

Philips' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool is a non-invasive diagnostic reading software intended to provide cardiologists and radiologists with an optimized non-invasive application to provide accurate quantification and characterization of coronary plaque. It is an interactive post-processing tool for viewing and analyzing cardiac CT image data for determining the presence and extent of coronary plaques.

7. Comparison to Predicate Devices

In the opinion of Philips Philips' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool is of comparable type and substantially equivalent to the legally marketed devices described in paragraph 3 above.

The "Philips' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool" is manufactured in accordance with the Quality System Regulations (QSR), 21 CFR Part 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' Comprehensive Cardiac Analysis (CCA) Plaque Assessment tool" CT scanner is substantially equivalent in safety and effectiveness to the predicate devices identified in paragraph 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

UL International Germany GmbH
% Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

OCT - 9 2009

Re: K092747
Trade/Device Name: Philips Comprehensive Cardiac Analysis (CCA) Plaque Assessment Tool
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 23, 2009
Received: September 25, 2009

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 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" (21CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine 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): K092747 Page 1 of 1

Device Name: **Philips Comprehensive Cardiac Analysis (CCA) - Plaque Assessment tool**

Indications for Use:

The Plaque Analysis option is a non-invasive diagnostic reading software intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques.

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 K092747