MAR - 9 2012

510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21 CFR. Part 807.92.

1) Submitter's name, address, telephone number, contact person

Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA 01810-6302 ,
Penny Greco, Regulatory Affairs Specialist
Tel: (978) 659-4615
Fax (978) 975-7324
E-mail: penny.greco@philips.com

Date prepared: February 15, 2012

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	QLAB CMQ Plug-in
Classification Name:	CFR 892.2050, system, image processing, radiological, 90 LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the modified QLAB CMQ Plug-in is substantially equivalent to the previously cleared QLAB TMQ Plug-in marketed pursuant to K070792, and K042540. Originally marketed as TMQ, the QLAB CMQ Plug-in was documented in a letter to file as described in QLAB 510(k) K110414.

4) Device Description

QLAB Quantification software is available either as a stand-alone product that can function on a standard PC, on board a dedicated workstation, or on-board Philips' ultrasound systems. It can be used by trained healthcare professionals for the on-line and off-line review and quantification of ultrasound studies in healthcare facilities/hospitals.

The QLAB Quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products. Cardiac Motion Quantification (CMQ) is a plug-in included in Philips QLAB Quantification software.

The CMQ plug-in is an application within QLAB intended to provide cardiac motion quantification. QLAB Quantification software is intended for use in healthcare facilities/hospitals by trained healthcare professionals.

QLAB CMQ modifications were implemented to provide clients with improved reproducibility and consistency between users, as well as to provide users with a reduction of workflow steps. The modifications described in this Special 510(k) submission do not alter the intended use of the QLAB Quantification software with the CMQ plug-in.

5) Indications for Use

QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Healthcare ultrasound products.

6) Technological characteristics

The QLAB Quantification software with the modified CMQ plug-in has the same technological characteristics as the legally marketed device.

7) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. The CMQ modifications were tested in accordance with Philips verification and validation processes. Verification and validation data support the following non-clinical claims for the modified CMQ software relative to the unmodified CMQ software:

1. Improved workflow - fewer mouse clicks for typical assessment;
2. Improved workflow - decreased average time for typical assessment;
3. Decreased intra-observer variability of assessments; and
4. Decreased inter-observer variability of assessments.

Verification and validation testing concluded that the modified CMQ is safe and effective and introduced no new risks.

8) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB Quantification software with the modified CMQ plug-in.

9) Conclusions

Verification, validation, and testing activities, where required to establish the performance, functionality, and reliability characteristics of the modified device with respect to the predicate were performed. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Testing performed demonstrates that the QLAB Quantification software with modified CMQ plug-in meets all defined reliability requirements and performance claims.

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

MAR - 9 2012

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K120525
Trade/Device Name: Philips QLAB Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2012
Received: February 22, 2012

Dear Mr. Job:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/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/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K120525

Device Name: Philips QLAB Quantification Software

Indications for Use:

QLAB Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

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 OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K120525