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FEB 17 2004

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

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

Steve Singlar
Regulatory Submissions Manager
Philips Ultrasound
3000 Minuteman Road
Andover, MA 01810-1099
Telephone: (978) 659-1201
Facsimile: (978) 975 7324
E-mail: Steve.Singlar@Philips.com

Date prepared: 15 January 2004

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 Quantification

Classification Name: Picture Archiving and Communications System, Class II

3) Device Description

QLAB version 3.0 adds a Cardiac 3DQ Plug-in (3D viewer with 3D measurements), GI 3D viewer Plug-in and an MVI Plug-in to the cleared QLAB version 2.0.

The Cardiac 3DQ plug-in provides a means of opening, displaying, manipulating and measuring 3D image files from currently cleared Philips Ultrasound systems The 3DQ plug-in also allows distance, area, volume and mass measurements from MultiPlanar Reconstruction (MPR) images derived the 3D data sets. The software also provides a means of exporting the data generated by the plug in module in a form accessible to the end user.

GI (General Imaging) 3D Viewer Plug-in reads DICOM compliant files generated by currently cleared Philips Ultrasound systems. It contains tools for changing 3D volume rendering parameters. The volume rendering is done using the rendering engine shipping with the Boris Platform and Philips HDI 5000. Therefore the main volume rendering controls are the same as on the imaging system.

MVI (Microvascular Imaging) Plug-in reads DICOM compliant files generated by the Philips Boris Platform and the Philips HDI 5000 Platforms. It performs a Maximum Intensity Projection convolution of the cine' information and allows viewing of the processed information. It provides tools for export of the resulting information in a standard AVI file format for use in presentations. The processing is accomplished exactly as in the Predicate device (HDI 5000) with the exception that there are no user selectable processing changes possible.

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4) Performance Standards

No performance standards for PACS systems or components have been issued under the authority of Section 514. The QLAB software has been designed to comply with the following voluntary standards:

- MSDN - Microsoft Developer's Network October 2001
- ISO Joint Photographic Experts Group (JPEG) Image Compression Standard

5) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB software.

6) Substantially Equivalent Devices

Philips Ultrasound believes that the QLAB software is substantially equivalent to other commercially available products, specifically Philips M2424 Diagnostic Ultrasound System and the TomTec Cardio-View.

7) Software

Software development for the QLAB software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product.

8) Conclusions

The QLAB software is designed and manufactured to meet United States and international standards for the display and quantification of images acquired on Phillips Ultrasound devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. The QLAB software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2004

Philips Ultrasound, Inc.
% Ms. Laura Danielson
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K040227
Trade/Device Name: QLAB Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 30, 2004
Received: February 2, 2004

Dear Ms. Danielson:

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 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

2 FDA Indication for Use Form

510(k) Number: ~~Unknown~~ K040227

Device Name: QLAB Quantification Software with Cardiac 3DQ Plug-in, 3D General Imaging Viewer Plug-in and a Microvascular Imaging Plug-in.

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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040227