

B - Administrative Information

APR - 6 2007

1 510(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

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Date prepared: March 16, 2007

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 6.0 adds the QLAB MVQ Plug-in and QLAB TMQ/TMQA Plug-ins to the cleared QLAB software.

QLAB MVQ Plug-in (MVQ stands for Mitral Valve Quantification)

Tool to assess lengths, distances, areas, volumes and angles of mitral valve structures from a Philips Ultrasound system 3D dataset.

QLAB TMQ/TMQA Plug-ins (TMQ and TMQA stands respectively for Tissue Motion Quantification and Tissue Motion Quantification Advanced)

TMQ and TMQA plug-ins are an addition to the existing 2DQ plug-in already described on the iE33 510(k) submission K042540. The QLAB TMQ/TMQA plug-ins provide ultrasound tracking algorithm using pattern-matching method of wall

lengthening, shortening and displacement in a set of 2D image. Radial, longitudinal, circumferential, lengths and strains are computed as well as rotation and rotation gradient and absolute speed. TMQ provides only one myocardial layer and 17 segmentation model only; TMQA will provide Multi Myocardial Layers and a choice of Segmentation on and off. CAK (Cardiac Annular Kinesis) feature is an addition to the existing 2DQ plug-in already described on the iE33 510(k) submission K042540. CAK will be a feature of existing 2DQ plug-in as well as TMQ and TMQA plug-ins. CAK is Quick survey tool of global function assessment.

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:

- JPEG (lossy and lossless): ITU-T T.81, ISO/IEC IS 10918-1

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 6.0 software with

- MVQ plug-in is substantially equivalent to other commercially available products, specifically TomTec 4D MV –Assessment software.
- TMQ/TMQA plug-in is substantially equivalent to other commercially available products, specifically GE Healthcare AFI software.

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 the legally marketed devices cleared through premarket notification and no new issues of safety or effectiveness are raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Philips Medical Systems
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

APR - 6 2007

Re: K070792
Trade/Device Name: QLAB Quantification Software
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 21, 2007
Received: March 22, 2007

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 either class II (Special Controls) or class III (Premarket Approval), 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.



Protecting and Promoting Public Health

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.

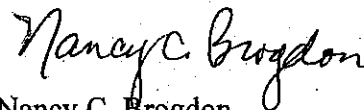
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



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:

Device Name: QLAB 6.0 Quantification Software with additional MVQ plug-in, and TMQ/TMQA plug-ins.

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 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 G. Simpson

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

510(k) Number K070792