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

June 7th, 2018

Re: K181264
Trade/Device Name: QLAB Advanced Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 11, 2018
Received: May 14, 2018

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

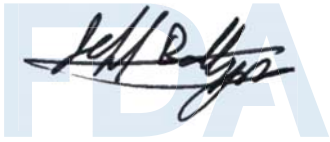
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181264

Device Name

QLAB Advanced Quantification Software

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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


Primary Contact: Penny Greco
Philips Ultrasound, Inc.
3000 Minuteman Road
Andover, MA 01810-6302
Email: penny.greco@philips.com
Tel: (508) 843-0282
Fax (978) 975-7324

Secondary Contact: Zhengbin Xu
Philips Ultrasound, Inc.
Email: Zhengbin.xu@philips.com


Date prepared: March 21, 2018

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 system

Proprietary Name: QLAB Advanced Quantification Software

Classification Name: 21 CFR 892.2050, system image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Primary Predicate Device

| | | |
|---|---|---|
| QLAB Modifications | K171314 | 05/30/2017 |

Reference Devices

| | | |
|---|---|---|
| QLAB Quantification Software with Heart Model | K130159 | 05/13/2013 |
| QLAB Quantification 10.0 Modifications | K132165 | 08/09/2013 |

Philips Ultrasound believes that the QLAB 11.0 modifications which are the subject of this 510(k) are substantially equivalent to QLAB K171314.

| | | |
|---|---|---|
| Philips Ultrasound, Inc. | Traditional 510(k)<br>**QLAB Advanced Quantification Software Modifications** | |

4) Device Description

Philips QLAB Advanced Quantification software (QLAB) is designed to view and quantify image data acquired on Philips ultrasound systems. QLAB is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' ultrasound systems. It can be used for the off-line review and quantification of ultrasound studies.

QLAB software provides basic and advanced quantification capabilities across a family of PC and cart based platforms. QLAB software functions through Q-App modules, each of which provides specific capabilities.

QLAB builds upon a simple and thoroughly modular design to provide smaller and more easily leveraged products.

Philips Ultrasound is submitting this 510(k) to address QLAB 11.0 modifications which include:

- Dynamic Heart Model (DHM) an enhancement to the Heart Model Quantification application that provides tracking of the entire cardiac cycle
- QLAB functionality upgraded to the HSDP Platform 2 from the HSDP Platform 1
- Q-Store Shared central database supporting multiple clients.

5) Intended Use

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

6) Technological comparison to predicate devices

The QLAB Advanced Quantification software with the modified Q-Apps has the same technological characteristics as the legally marketed device.

| **Proposed QLAB Dynamic Heart Model (DHM)** | **Currently Marketed Predicate QLAB Heart Model (K171314)** | **Explanation of Differences** |
|---|---|---|
| • The DHM Q-App is an application within QLAB intended to provide quantification of 3D cardiac images | • Heart Model | Dynamic Heart Model is an enhancement to the current Heart Model (K171314/ K132165/K130159) application that provides tracking of the entire cardiac cycle and expands the measurements |
| • HSDP Platform 2 | • HSDP Platform 1 | The HSDP platform has been upgraded to platform 2 to provide customers with:<br>• Better installation support. Ease of use and support of non SQL database (SQLite )<br>• Support for Remote database and storage feature<br>• Support for advanced database operations like rebuild, relocate and recreate without having to reinstall |

| Proposed QLAB Dynamic Heart Model (DHM) | Currently Marketed Predicate QLAB Heart Model (K171314) | Explanation of Differences |
|---|---|---|
| | | • Better support for HTML5 reporting feature to make it seamless with on cart reporting<br>• Off the shelf integration with PSC (latest service tool platform)<br>• Philips identity UI support |
| Q-Store Shared central database that supports multiple clients. | No central database | Q-Store is a central database and storage solution. |
| QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems. The modifications to the currently marketed QLAB do not affect the safety and efficacy of the proposed QLAB 11.0 Advanced Quantification with Dynamic Heart Model application, the HSDP platform2 or Q-Store. | | |

7) Determination of Substantial Equivalence

Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. The QLAB 11.0 modifications were tested in accordance with Philips internal processes. Verification and software validation data support the proposed modified QLAB 11.0 software relative to the currently marketed unmodified QLAB software.

Design Control activities to assure the safe and effective performance of the modified Q-Apps included, but were not limited to:

- Requirements Review
- Design Review
- Risk Management
- Software Verification and Validation

Software Verification and Validation testing were used to support substantial equivalence of the modified QLAB 11.0 to the predicate device.

Summary of Clinical Tests

QLAB 11.0 introduces no new indications for use, modes, features, or technologies relative to the predicate device (QLAB 10.8 K171314) that require clinical testing.

8) Conclusions

Software Verification and Validation activities required established the performance, functionality, and reliability characteristics of the modified QLAB software with respect to the predicate were performed. Testing performed demonstrated that the proposed QLAB 11.0 Advanced Quantification Software meets defined requirements and performance claims.

514 Performance Standards
There are no Sec. 514 performance standards for this device.

Prescription Status
This is a prescription device. The prescription device statement appears in the labeling.

Sterilization Site(s)
Not applicable. QLAB Advanced Quantification is a software only device.