Philips Healthcare
℅ Travis Catania
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL WA 98021

June 3, 2020

Re: K200974
Trade/Device Name: QLAB Advanced Quantification Software System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: April 10, 2020
Received: April 13, 2020

Dear Travis Catania:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K200974

Device Name
QLAB Advanced Quantification Software System

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.

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Section 8: 510(k) Summary

Philips QLAB Advanced Quantification Software System

This summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92

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

Sponsor: Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact Person: Travis Catania
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Secondary Contact: Hebe Sun
Senior Manager, Regulatory Affairs

Date Prepared April 10, 2020

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

Proprietary Name: QLAB Advanced Quantification Software System

Common Name: QLAB Advanced Quantification Software System
Automated Radiological Image Processing Software

Regulation Description:

Classification Description	21 CFR Section	Product Code
Automated Radiological Image Processing Software	892.2050	QIH

As stated in 21 CFR, part 892.2050, each of the generic types of devices that meet this classification description have been classified as Class II.

Device Class: Class II

3. Indications for Use

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

4. Device Description

The Philips QLAB Advanced Quantification Software System (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.

The purpose of this Traditional 510(K) Pre-market Notification is to introduce a new to introduce the new 3D Auto MV cardiac quantification application to the Philips QLAB Advanced Quantification Software, which was most recently cleared under K191647. The latest QLAB software version (launching at version 15.0) will include the new Q-App 3D Auto MV, which integrates the segmentation engine of the cleared QLAB HeartModel Q-App (K181264) and the TomTec-Arena 4D MV Assessment application (K150122) thereby providing a dynamic Mitral Valve clinical quantification tool.

5. Substantially Equivalent Devices

<u>Primary Predicate Device</u>		
Philips QLAB Advanced Quantification Software System	K191647	December 20, 2019
<u>Reference Predicate Device</u>		
TomTec Imaging Systems, GmbH TOMTEC-Arena TTA2	K150122	February 13, 2015

6. Technological Comparison to Predicate Devices

The QLAB Advanced Quantification Software System with the addition of the new Q-App entitled 3D Auto MV application has the same intended use and similar technological characteristics as the legally marketed primary QLAB System predicate device. A comparison of the proposed QLAB System (including 3D Auto MV application) to the currently marketed predicate QLAB System device and the reference predicate TomTec Imaging System TTA2 (4D MV Assessment application) are provided in the table below:

Table 1

Comparison of the proposed Philips QLAB System to the currently marketed and predicate devices: Philips QLAB System and TomTec Imaging Systems TTA2 System

	Subject Device	Predicate Device	Reference Predicate Device	Explanation of Differences
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	TOMTEC Imaging Systems, GmbH	None
Trade Name	QLAB System	QLAB System	Arena TTA2	None
Feature	3D Auto MV	HeartModel	4D MV-Assessment	None
510(k) Number	Pending	K191647	K150122	None
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050	Regulation Number, Regulation Name, Classification, and Product Code are identical between subject device and primary predicate device.
Regulation Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	
Classification	Class II	Class II	Class II	
Product Code(s)	QIH	QIH	LLZ	
Indications for Use	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	Indications for use of TOMTEC-Arena software are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physicians in the diagnosis.	The Indications for Use of the subject QLAB System and the primary predicate QLAB System are identical and have not been changed from the previous clearance of this system. The Philips QLAB and TOMTEC Arena TTA2 Systems are similar in regards to image display and quantification purposes to the end user.
System Components	Software only system	Software only system	Software only system	The System Components of the subject QLAB System and predicate devices identified are identical as all devices are software only

					systems.
Software Design	Application Description	The 3D Auto MV Q-App is a semi-automatic tool that essentially is an integration of the machine-learning derived segmentation engine of the QLAB HeartModel and the TOMTEC-Arena TTA2 4D MV-Assessment application thereby providing a dynamic Mitral Valve clinical quantification tool.	The HeartModel Q-App provides a semi-automatic 3D anatomical border detection and identification of the heart chambers for the end-diastole (ED) and end-systole (ES) cardiac phases.	The TOMTEC Arena TTA2 4D MV-Assessment application provides a morphological and functional assessment of the mitral valve based on a surface model of the mitral valve anatomy.	The subject 3D Auto MV Q-App combines the HeartModel auto-segmentation technology with TOMTEC Arena TTA2 4D MV-Assessment application in order to provide initial mitral valve landmark proposals to the end user followed by reporting mitral valve measurements to the user.
	Quantification Technology of the MV	Integrates the Heartmodel auto-segmentation technology with TOMTEC Arena TTA2 4D MV-Assessment algorithm for initial landmark identification and MV quantification.	Semi-automatic border detection and identification of heart chambers.	Functional assessment of the mitral valve based on an MV surface model.	The subject 3D Auto MV application integrates the semi-automatic border detection functionality of HeartModel and the functional mitral valve assessment measures of 4D MV-Assessment to provide a comprehensive MV assessment tool.
	Contour Generation	3D surface model is created semi-automatically using machine learning algorithm without user interaction. User is able to edit, accept, or reject the initial landmark proposals of the mitral valve anatomical locations.	3D surface model is created semi-automatically without user interaction. User is required to edit, accept, or reject the contours before proceeding with the workflow.	3D surface model is created based on user defined anatomical landmarks. User is able to edit the contour of the surface model before proceeding with the workflow.	Workflow improvements for user convenience in initial model display and landmark proposal. Algorithm Training procedures is the same between the subject 3D Auto MV and the predicate HeartModel, with the exception being that the algorithm is being applied to the LV in Heartmodel, while

					in 3D Auto MV the algorithm is applied to the MV.
Measurement Parameters	Standard MV Parameters	✹AP Diameter (cm) ✹AL-PM Diameter (cm) ✹Sphericity Index (AP / AL-PM) ✹Intertrigonal Distance (cm) ✹Commissural Diameter (cm) ✹D-Shaped Annulus Perimeter (cm) ✹Annulus Height (cm) ✹Non-planar Angle (degrees) ✹Tenting Volume (cm^3) ✹Coaptation Depth (mm) ✹Tenting Area (cm^2) ✹Angle AAo-AP (degrees) ✹Maximum Prolapse Height (mm) ✹Maximum Open Coaptation Gap (mm) ✹Maximum Open Coaptation Width (mm) ✹Anterior Leaflet Area (cm^2) ✹Posterior Leaflet Area (cm^2) ✹Distal Anterior Leaflet Angle (degrees) ✹Posterior Leaflet Angle (degrees) ✹Anterior Leaflet Length (cm) ✹Posterior Leaflet Length (cm) ✹C-Shaped Annulus (cm)	No standard mitral valve (MV) quantification parameters included as part of this application.	✹AP Diameter (cm) ✹AL-PM Diameter (cm) ✹Sphericity Index ✹Intertrigonal Distance (cm) ✹Commissural Diameter (cm) ✹Annulus Height (cm) ✹Non-planar Angle (degrees) ✹Tenting Volume (cm^3) ✹Coaptation Depth (mm) ✹Tenting Area (cm^2) ✹Angle AAo-AP (degrees) ✹Anterior Leaflet Area (cm^2) ✹Posterior Leaflet Area (cm^2) ✹Distal Anterior Leaflet Angle (degrees) ✹Posterior Leaflet Angle (degrees) ✹Anterior Leaflet Length (cm) ✹Posterior Leaflet Length (cm) ✹C-Shaped Annulus (cm)	The 3D Auto MV application introduces the D-Shaped Annulus Perimeter, Maximum Prolapse Height, and Maximum Open Coaptation Gap and Width measurements as additional measures to further define the mitral valve anatomy. All other measurements are identical to the predicate 4D MV-Assessment application.
	2D MV Parameters	✹D-Shaped Annulus Area (cm^2) ✹Annulus Area (cm^2) ✹Anterior Closure Line Length (cm) ✹Posterior Closure Line Length (cm)	No 2D mitral valve (MV) quantification parameters included as part of this application.	✹Annulus Area (cm^2) ✹Anterior Closure Line Length (cm) ✹Posterior Closure Line Length (cm)	The 3D Auto MV application introduces the D-Shaped Annulus Area measurement as an additional measure to further define the mitral valve anatomy. All other measurements are identical to the predicate 4D MV-

					Assessment application.
	3D MV Parameters	✹Saddle Shaped Annulus Area (cm^2) ✹Saddle Shaped Annulus Perimeter (cm) ✹Total Open Coaptation Area (cm^2) ✹Anterior Closure Line Length (cm) ✹Posterior Closure Line Length (cm)	No 3D mitral valve (MV) quantification parameters included as part of this application.	✹Saddle Shaped Annulus Area (cm^2) ✹Saddle Shaped Annulus Perimeter (cm) ✹Anterior Closure Line Length (cm) ✹Posterior Closure Line Length (cm)	The 3D Auto MV application introduces the Total Open Area measurement as an additional measure to further define the mitral valve anatomy. All other measurements are identical to the predicate 4D MV-Assessment application.

7. Non-Clinical Testing

The proposed modifications (the introduction of the 3D Auto MV application) to the subject Philips QLAB Advanced Quantification Software System were tested in accordance with Philips internal processes. Verification and software validation test data are provided to support the latest QLAB software release (QLAB 15.0) relative to the currently marketed unmodified QLAB software.

Design Control activities to assure the safe and effective performance of the modified QLAB System Q-App include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications
- Design Reviews
- Software Verification and Validation

Non-clinical V&V testing also included the 3D Auto MV Algorithm Training and the subsequent Validation Study performed for the proposed 3D Auto MV clinical application.

Software Verification and Validation testing were used to support substantial equivalence of the modified QLAB software release version 15.0 (specifically the 3D Auto MV application) to the predicate QLAB software release version 13.0 device.

8. Clinical Testing

The subject Philips QLAB Advanced Quantification Software System did not require clinical data in order to make a determination for substantial equivalence when compared to the predicate device(s).

9. Conclusion

Based on the conformance to standards, development under Philips Ultrasound's Quality Management System, the successful verification and validation testing, Philips Ultrasound believes that the proposed Philips QLAB Advanced Quantification Software System is substantially equivalent to the predicate device Philips QLAB System (K191647) and TomTec Imaging Systems TTA2 (150122). Testing performed demonstrated that the proposed QLAB System with the 3D Auto MV application meets the defined requirements and performance claims.