Philips Healthcare
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
SAINT PAUL, MN 55114

June 18, 2019

Re: K190913
Trade/Device Name: QLAB Advanced Quantification Software 13.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 6, 2019
Received: June 10, 2019

Dear Mark 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. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190913

Device Name
QLAB Advanced Quantification Software 13.0

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.

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☐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: Arti Arvind
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Date prepared: June 17, 2019

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 13.0

Classification Name: 21 CFR 892.2050, System, Image Processing, Radiological,
Product code LLZ, Class II

3) Substantially Equivalent Devices

Primary Predicate Device

QLAB Advanced Quantification Software 11.0	K181264	June 7, 2018

Reference Devices

TomTec-Arena TTA2	K150122	February 13, 2015

Philips Ultrasound believes that the QLAB 13.0 modifications which are the subject of this 510(k) are substantially equivalent to QLAB 11.0 cleared under K181264.

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.

The primary modification to QLAB 13.0 includes the addition of the following applications:

- Philips acquired TOMTEC Imaging Systems GmbH in 2017, and the modified QLAB 13.0 release integrates the currently marketed TomTec-Arena TTA2 AutoSTRAIN application (cleared under K150122 for the Left Ventricle) within the Philips QLAB portfolio as **AutoStrain LV** (Left Ventricle) with some workflow improvements.
- **AutoStrain LA** (Left Atrium) application combines the functionality of the cleared TomTec-Arena 2D Cardiac Performance Analysis (2D CPA cleared under K150122) and the technology of the cleared TomTec-Arena AutoSTRAIN (cleared under K150122) and provides an easy LA strain solution for user convenience.
- **AutoStrain RV** (Right Ventricle) application combines the functionality of the cleared TomTec-Arena 2D Cardiac Performance Analysis (2D CPA cleared under K150122) and the technology of the cleared TomTec-Arena AutoSTRAIN (cleared under K150122) and provides an easy RV strain solution for user convenience.

5) Indications for 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 intended use and technological characteristics as the legally marketed predicate device. A comparison of the proposed QLAB applications (AutoStrain LV, AutoStrain LA, AutoStrain RV) to the currently marketed predicate device (QLAB) and reference device (TomTec-Arena TTA2) are provided in the tables below:

Feature	Currently Marketed Predicate QLAB (Predicate Device - K181264)	Currently Marketed Reference TomTec-Arena TTA2 (Reference Device - K150122)	Proposed QLAB AutoStrain LV, LA, RV (Modified Device)	Explanation of Differences
Indication for Use	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 TTA2 software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physicians in the diagnosis	Same as QLAB (K181264)	Not applicable

AutoStrain LV

Feature	Currently Marketed Predicate QLAB Auto Cardiac Motion Quantification (aCMQ) (K181264)	Currently Marketed Reference TomTec-Arena TTA2 AutoSTRAIN (Reference Device - K150122)	Proposed QLAB AutoStrain LV (Modified Device)	Explanation of Differences
Application description	aCMQ provides an angle-independent analysis of regional myocardial-tissue velocity, displacement, strain, and strain rate, using the speckle tracking technology. It generates measurements of the global and regional functions of the left ventricle.	AutoSTRAIN is a quantification tool of global and regional function based on contour detection and tracking. The tool automatically quantifies global and regional strain based on apical 4-chamber, 3-chamber and 2-chamber views of the left ventricle.	Same as AutoSTRAIN on TOMTEC-ARENA	Reason for change: AutoStrain LV functionality enables a simplified workflow when compared to QLAB aCMQ (originally cleared under K132165)

Speckle Tracking of the ROI per frame	Comparable feature available	Automatically tracks the ROI of the wall motion per frame using speckle tracking technology. User is able to edit the ROI after tracking.	Same as AutoSTRAIN on TomTec-Arena.	
Automatic view recognition to detect chamber views	Manual view selection to detect chamber view.	Manual view selection to detect chamber view.	The application uses view recognition to automatically assign labels. The user is able to overwrite the automatic assignation of labels.	Workflow simplified on QLAB for user convenience
Calculation of GLS from three views (global strain analysis)	Same calculation available	GLS is calculated based on the Tracked contours per view and as average according to the length-of-line method.	Same as AutoSTRAIN on TomTec-Arena.	

AutoStrain LA

Feature	Currently Marketed Predicate QLAB (K181264)	Currently Marketed Reference TomTec-Arena TTA2 2D Cardiac Performance Analysis - 2D CPA (Reference Device - K150122)	Proposed QLAB AutoStrain LA (Modified Device)	Explanation of Differences
Application description	Strain quantification of LA chamber is not available on QLAB	2D CPA speckle tracking algorithm supports the calculation of 2D - contour models of the endocardial of the LA. Corresponding	The AutoStrain LA provides left atrial strain measurements from apical four-chamber (A4C).	AutoStrain LA combines the functionality of 2D CPA and the technology of AutoSTRAIN (for LV) cleared under

		velocities, displacements, strains, strain rates and functional parameters can be derived		K150122 to provide an easy LA strain solution for user convenience.
Speckle Tracking of the ROI per frame	Option not available for LA chamber	A Speckle tracking algorithm tracks the ROI of the wall motion per frame. User is able to edit the ROI after tracking.	Similar speckle tracking algorithm tracks the ROI of the wall motion per frame. User is able to edit the ROI after tracking.	Speckle tracking technology used for TomTec-Arena 2D CPA and AutoSTRAIN (for LV) has been adapted for the left atrial chamber for AutoStrain LA
Calculation of global strain analysis from one view	Option not available for LA chamber	Left Atrial Strain is calculated based on the tracked contour	Same as 2D CPA. Additionally, conduit and contraction Strain is calculated.	

AutoStrain RV

Feature	Currently Marketed Predicate QLAB (K181264)	Currently Marketed Reference TomTec-Arena TTA2 2D Cardiac Performance Analysis - 2D CPA (Reference Device - K150122)	Proposed QLAB AutoStrain RV (Modified Device)	Explanation of Differences
Application description	Strain quantification of RV chamber is not available on QLAB	2D CPA speckle tracking algorithm supports the calculation of 2D - contour models of the endocardial border of the RV. Corresponding velocities, displacements,	The AutoStrain RV provides right ventricle strain measurements from apical four-chamber (A4C) views.	AutoStrain RV combines the functionality of 2D CPA and the technology of AutoSTRAIN (for LV) cleared under K150122 to provide an easy RV strain

		strains, strain rates are derived.		solution for user convenience.
Speckle Tracking of the ROI per frame	Option not available for RV chamber	A Speckle tracking algorithm tracks the ROI of the wall motion per frame. User is able to edit the ROI after tracking.	Similar speckle tracking algorithm tracks the ROI of the wall motion per frame. User is able to edit the ROI after tracking.	Speckle tracking technology used for TomTec-Arena 2D CPA and AutoSTRAIN (for LV) has been adapted for the right ventricular chamber for AutoStrain RV
Calculation of global strain analysis from one view	Option not available for RV chamber	RV global Strain and Freewall strain is calculated based on the tracked contour	Same as 2D CPA on TomTec-Arena	

Summary of changes documented via Letter to File since QLAB 11.0 release (K181264)

Feature/ Modification incorporated in QLAB software since QLAB 11.0 release	**Feature / Modification**
QLAB 12.0	Integrate the currently marketed TomTec-Arena AutoSTRAIN (for Left Ventricle) application (cleared under K150122) on the Philips QLAB platform. Application description: AutoSTRAIN is a quantification tool of global and regional function based on contour detection and tracking. The tool automatically quantifies global and regional strain based on apical 4-chamber, 3-chamber and 2-chamber views of the left ventricle
QLAB 13.0	Integrate the currently marketed TomTec-Arena Mitral Valve Assessment (4D MVA) application (cleared under K150122) on the Philips QLAB platform. Application description: The 4D MVA provides a morphological and functional analysis of mitral valves for 3D loops. The application generates models of anatomical structures such as MV annulus, leaflets, and the closure line.

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

13.0 Advanced Quantification Software with AutoStrain LV, AutoStrain LA, AutoStrain RV clinical applications.

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 13.0 modifications were tested in accordance with Philips internal processes. Verification and software validation data support the proposed modified QLAB 13.0 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 not limited to the following:

- 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 13.0 to the predicate device.

Summary of Clinical Tests

QLAB 13.0 does not introduce new indications for use, modes, or features relative to the predicate (K181264) that require clinical testing.

8) Conclusions

Software Verification and Validation activities required to establish 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 13.0 Advanced Quantification Software meets defined requirements.

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.