Philips Healthcare
Eri Gremi
Philips Ultrasound Inc.
3000 Minuteman Road
Andover, MA 01810-6302

December 20, 2019

Re: K191647
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: QIH
Dated: November 22, 2019
Received: November 25, 2019

Dear Eri Gremi:

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)*
K191647

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: Eri Gremi
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Date prepared: November 22 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:	QIH, Class II

3) Substantially Equivalent Devices

Primary Predicate Device		
QLAB Advanced Quantification Software	K181264	June 7, 2018
Reference Device		
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 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.

The subject QLAB 3D Auto RV application integrates the segmentation engine of the cleared QLAB HeartModel (K181264) and the TomTec-Arena 4D RV-function (cleared under K150122) thereby providing a dynamic Right Ventricle clinical functionality. The proposed 3D Auto RV application is based on the automatic segmentation technology of HeartModel applied to the Right Ventricle, and uses machine learning algorithms to identify the endocardial contours of the Right Ventricle.

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 devices. A comparison of the proposed QLAB 3D Auto RV application 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 3D Auto 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

Feature	Currently Marketed Predicate QLAB HeartModel (K181264)	Currently Marketed Reference TomTec-Arena TTA2 4D RV (Reference Device - K150122)	Proposed QLAB 3D Auto RV (Modified Device)	Explanation of Differences
Application description	The HeartModel provides 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 4D RV-Function provides a morphological and functional assessment of the right ventricle based on a surface model of the RV.	The 3D Auto RV Q-App is an integration of the segmentation engine of the QLAB HeartModel and the TomTec-Arena 4D RV-Function thereby providing a dynamic Right Ventricle clinical functionality.	Integrates HeartModel auto-segmentation technology with TomTec Arena's 4D-RV algorithm for RV border placement.
Quantification Technology of RV	Semi-automatic border detection and identification of LV and LA chambers	Functional assessment of RV based on a RV surface model.	Integrates HeartModel auto-segmentation technology with TomTec Arena's 4D-RV algorithm for RV border placement	Anatomical enhancement by Right Ventricle
2D RV measurement parameters	No RV parameters	▪ RVDd base (RVD1): Right Ventricle Distance base (mm) ▪ RVDd mid (RVD2): Right Ventricle Distance medial (mm) ▪ RVLd (RVD3): Right Ventricle Distance Longitudinal (mm) ▪ TAPSE: Tricuspid annular plane systolic excursion (mm) ▪ FAC: Fractional area change (%) ▪ RVLS (free wall): right ventricular longitudinal strain (free wall) (%) ▪ RVLS (Septum): right ventricular longitudinal strain (septum) (%)	▪ RVDd base (RVD1): Right Ventricle Distance base (mm) ▪ RVDd mid (RVD2): Right Ventricle Distance medial (mm) ▪ RVLd (RVD3): Right Ventricle Distance Longitudinal (mm) ▪ TAPSE: Tricuspid annular plane systolic excursion (mm) ▪ FAC: Fractional area change (%) ▪ RVLS (free wall): right ventricular longitudinal strain (free wall) (%) ▪ RVLS (Septum): right ventricular longitudinal strain (septum) (%)	Identical to 4D RV predicate
2D RV calculated parameters	No RV parameters	▪ Global strain ▪ TAPSE: MMode measurement for movement of TV between ED and ES	▪ Global strain ▪ TAPSE: MMode measurement for movement of TV between ED and ES	Identical to 4D RV predicate

		▪ RV distance measurements: 3 distance measurements in the RV A4C in ED. ▪ RVD1: maximal short-axis dimension in the basal one third of the right ventricle ▪ RVD2: distance is measured on 50% of RVLd (RVD3) and parallel to the RVD1 ▪ RVD3: base–apex length ▪ Fractional area change (FAC)	▪ RV distance measurements: 3 distance measurements in the RV A4C in ED. ▪ RVD1: maximal short-axis dimension in the basal one third of the right ventricle ▪ RVD2: distance is measured on 50% of RVLd (RVD3) and parallel to the RVD1 ▪ RVD3: base–apex length ▪ Fractional area change (FAC)	
3D RV measurement parameters	No RV parameters	▪ EDV: End-diastolic Volume ▪ EDVI: End-diastolic Volume Index ▪ ESV: End-systolic Volume ▪ ESVI: End-systolic Volume Index ▪ SV: Stroke Volume ▪ EF: Ejection Fraction	▪ EDV: End-diastolic Volume ▪ EDVI: End-diastolic Volume Index ▪ ESV: End-systolic Volume ▪ ESVI: End-systolic Volume Index ▪ SV: Stroke Volume ▪ EF: Ejection Fraction	EDV measurement includes semi-automatic function introduced in 3DAutoRV. All other measurements identical to 4D RV predicate.
3D RV calculated parameters	No RV parameters	▪ EF: Ejection Fraction ▪ SV: Stroke Volume	▪ EF: Ejection Fraction ▪ SV: Stroke Volume	Identical to 4D RV predicate
Contour Generation	3D surface model is created semi-automatically without user interaction. User is required to edit, accept or reject the contours	3D surface model is created based on user defined anatomical landmarks. User is able to edit the contour of the surface model.	3D surface model is created semi-automatically using machine learning algorithms without user interaction. User is able to edit, accept or reject the contours or the anatomical landmarks.	Workflow improvements for user convenience. Algorithm Training procedure is same between the subject and the predicate HeartModel, except that the algorithm is applied to LV in HeartModel, while to RV in subject 3D auto RV.

7) Determination of Substantial Equivalence

Non-clinical performance data

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

Non-clinical V&V testing also included the Machine Learning Algorithm Training and the subsequent Validation Study performed for the proposed 3D Auto RV clinical applications.

Software Verification and Validation testing were used to support substantial equivalence of the modified QLAB 13.0 to the predicate device.

The results of a validation study show that the overall performance of the 3D Auto RV software generates RV end diastolic volume error rates below 15% for every data set tested compared to the predicate 4D RV. A root mean square error (RMSE) analysis showed that in comparison to the predicate 4D RV, 3D Auto RV measured end diastolic RV volumes with 8.3 ml RMSE, end systolic RV volumes with 2.7 ml RMSE, and RV ejection fraction with 2.7% RMSE. Test datasets were segregated from training data sets. The results of the validation show that when used as intended, the healthcare professional was able to successfully determine which contours required revision and was capable of revising in the "tracking revision" screen prior to accepting the measurements for a report to create accurate measurements of the RV volume.

An external study published in the Journal of the American Society of Echocardiography which concludes that 3D Auto RV provides an accurate and highly reproducible quantification not needing any revision in one-third of patients and needing only minor revisions in the rest of patients. The users were able to discern the patients images which needed manual editing on all cases. Ground truth in this study was considered to be the cross-modality CMR. 3D Auto RV results all showed less than 15% difference from the CMR measurements of RV volume.

Summary of Clinical Tests

No clinical testing conducted in support of substantial equivalence.

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
Not applicable. QLAB Advanced Quantification is a software only device.

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 and performance claims. Therefore, Philips concludes that the subject device is substantially equivalent to the predicate in terms of safety and effectiveness.