Philips Ultrasound, Inc.
% Hebe Sun
Regulatory Affairs Manager
22100 Bothell Everett Highway
BOTHELL WA 98021

September 20, 2020

Re: K200603
Trade/Device Name: AAA Model
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 12, 2020
Received: August 17, 2020

Dear Hebe Sun:

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 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200603

Device Name
AAA Model

Indications for Use *(Describe)*
The AAA Model is a software application designed to view and quantify 3D image data acquired by Philips diagnostic ultrasound systems for use in measuring the anterior-posterior diameter of abdominal aortic aneurysms. Optionally, lateral diameter, maximum diameter, and partial volume of an abdominal aortic aneurysm can also be provided. It is intended to be used by trained and qualified healthcare professionals in clinics, hospitals, and clinical point-of-care facilities.

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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510(k) Summary

THIS SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

IS SUBMITTED IN ACCORDANCE WITH 21CFR § 807.92

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

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

Contact: Hebe Sun

Title: Sr. Regulatory Affairs Manager

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Tel: 425-219-1223
Fax: 425-487-8666

Date prepared: Aug 11, 2020

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 name: Picture archiving and communications system

Proprietary name: AAA Model

Regulation Number: 21 CFR 892.2050

Classification name: System, Image Processing, Radiological

Product code: LLZ,

Classification: Class II

3. **Indications for Use**

The AAA Model is a software application designed to view and quantify 3D image data acquired by Philips diagnostic ultrasound systems for use in measuring the anterior-posterior diameter of abdominal aortic aneurysms. Optionally, lateral diameter, maximum diameter, and partial volume of an abdominal aortic aneurysm can also be provided. It is intended to be used by trained and qualified healthcare professionals in clinics, hospitals, and clinical point-of-care facilities.

4. **Device Description**

AAA Model for QLAB Advanced Quantification Software is a software application designed for structural measurements of an Abdominal Aortic Aneurism (AAA), including volume measurement and diameter measurements. AAA Model is designed to assist in monitoring a previously diagnosed Abdominal Aortic Aneurisms in two ways:

1) to follow the anteroposterior (AP) maximum diameter for a Native AAA, and
2) to follow the anteroposterior (AP) maximum diameter for a post-surgical AAA.

AAA model is not a computer-assisted detection (CADe) device, and does not use artificial intelligence or machine learning.

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. AAA Model is compatible with the Philips EPIQ Diagnostic Ultrasound System.

5. Substantially Equivalent Devices

Primary Predicate Device
GI-3DQ in QLAB Advanced Quantification Software K200974

Reference Device
VPQ in QLAB Advanced Quantification Software K121223

A comparison of technical characteristics for subject device and the currently marketed predicate device is provided on the following table.

Comparison of Technical Characteristics

	Primary Predicate	Reference Device	Subject Device	Explanation of Differences
Trade Name	**QLAB System**	**QLAB System**	**QLAB System**	**N/A**
Feature	**GI-3DQ**	**VPQ**	**AAA Model**	**N/A**
510(k) number	**K200974**	**K121223**	**K200603**	**N/A**
Product Code	QIH	LLZ	LLZ	Identical
Regulation Number and Regulation Name	21 CFR 892.2050; System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	21 CFR 892.2050; System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	21 CFR 892.2050; System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	Identical
Indication for Use	Philips QLAB Quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products	Philips QLAB Quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products. The Vascular Plaque Quantification (VPQ) plug-in provides protocol driven tools	Philips QLAB Quantification software application package is designed to view and quantify image data acquired on Philips ultrasound products. The AAA Model is a software application designed to view and quantify 3D image data	The primary predicate GI-3DQ in QLAB is intended to be used for computing 3D measurements for any regions of interest, which can be used in the situation of abdominal aortic aneurysm. The subject device, AAA model application in QLAB, is designed to measure diameter of a previously detected abdominal aortic aneurysm.

	Primary Predicate	Reference Device	Subject Device	Explanation of Differences
Trade Name	**QLAB System**	**QLAB System**	**QLAB System**	**N/A**
Feature	**GI-3DQ**	**VPQ**	**AAA Model**	**N/A**
510(k) number	**K200974**	**K121223**	**K200603**	**N/A**
		for performing a semi-automated analysis of plaques in the carotid artery.	acquired by Philips EPIQ Diagnostic ultrasound systems for use in measuring Anterio-posterior diameter. Optionally, Lateral diameter, Maximum diameter, and partial volume of the Abdominal Aorta Aneurysm can also be provided. It is intended to be used by trained and qualified healthcare professionals in clinics, hospitals, and clinical point-of-care facilities.	

	Primary Predicate	Reference Device	Subject Device	Explanation of Differences
Trade Name	**QLAB System**	**QLAB System**	**QLAB System**	**N/A**
Feature	**GI-3DQ**	**VPQ**	**AAA Model**	**N/A**
510(k) number	**K200974**	**K121223**	**K200603**	**N/A**
Application description	GI-3DQ computes linear measurements, area measurements, stacked contour volume measurements, and ellipsoid volume measurements, of any regions of interest that users select.	VPQ provides semi-automatic analysis of plaque in the carotid artery. it calculates plaque and lumen areas, and also the percent reduction for each tracked frame.	AAA generates semi-automatic structural measurements of abdominal aortic aneurysm, including volume and diameter measurements.	Predicate GI-3DQ is for general imaging analysis of any regions of interest, while subject device AAA is specifically designed for abdominal aortic aneurysm analysis. The impact of the difference in clinical application on device safety and effectiveness is addressed by the clinical performance study.
Contour Generation	Borders are created manually to create a 3D model.	Preliminary borders and 3D model are created automatically without user interaction. User is required to edit, accept or reject the contours.	Preliminary borders and 3D model are created automatically without user interaction. User is required to edit, accept or reject the contours prior to 3D volume and diameter measurements.	Subject device AAA semi-automated border detection function is equivalent to VPQ. User is required to accept border prior to calculation for all apps.

	Primary Predicate	Reference Device	Subject Device	Explanation of Differences
Trade Name	**QLAB System**	**QLAB System**	**QLAB System**	**N/A**
Feature	**GI-3DQ**	**VPQ**	**AAA Model**	**N/A**
510(k) number	**K200974**	**K121223**	**K200603**	**N/A**
Quantification Technology	Manual border tracing over multiple slices; Creates 3D mesh to derive volume measurement; diameter measurement done via manual distance measurement tool	Automated preliminary boarder detection; Creates 3D mesh to derive volume measurement; diameter measurement done via manual distance measurement tool	Automated preliminary boarder detection; creates 3D mesh and auto-segmentation of AAA to derive volume and diameter measurements once preliminary borders are confirmed by user	Both subject device and predicate create 3D mesh to derive volume measurement. The difference is predicate GI-3DQ use manual distance measurement tool for diameter measurement, while the subject device AAA can derive the diameter measurements from the 3D mesh and auto-segmentation of the 3D model. The impact of the difference on safety and effectiveness is addressed by the measurement accuracy test from bench performance testing
Measurement Parameters	This app computes linear measurements, area measurements, stacked contour volume measurements, and	This app calculates plaque and lumen areas, and also the percent reduction for each tracked frame.	AAA model provides Max Anteroposterior (AP) diameter, Max Lateral Diameter (LAT), Max any direction	The measurements function of AAA model, including the diameter measurement and volume measurement, is similar to GI3DQ.

	Primary Predicate	Reference Device	Subject Device	Explanation of Differences
Trade Name	**QLAB System**	**QLAB System**	**QLAB System**	**N/A**
Feature	**GI-3DQ**	**VPQ**	**AAA Model**	**N/A**
510(k) number	**K200974**	**K121223**	**K200603**	**N/A**
	ellipsoid volume measurements.		(MAD) diameter, and partial volume measurement.	

6. Nonclinical Performance Data

AAA Model was tested in accordance with Philips internal processes. Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Software verification and clinical performance accuracy data were used to support substantial equivalence of the AAA Model application to the predicate QLAB Advanced Quantification Software applications.

Bench Testing	Test Method	Sample	Acceptance Criteria	Result
Measurement Accuracy Verification	EPIQ diagnostic ultrasound system was used to take 3D ultrasound images of 3 phantoms with various diameter. AAA model was used to measure the AP/LAT/MAD diameter and partial volume.	7 samples were used for each measurement.	± 9% accuracy for volume measurement and ± 5% for all diameter measurements, with 90% confidence interval.	All measurements met the acceptance criteria.

7. Clinical testing

Clinical performance evaluation study showed that the aneurysm AP diameter measurement from AAA model is in agreement with the measurement from 2D ultrasound as the current standard of care, which supports that the performance of AAA model is appropriate for its intended use of AP diameter measurement for the evaluation of abdominal aorta aneurysm.

Clinical testing	Test Method	Sample	Acceptance Criteria	Result
Native AAA clinical evaluation	Native AAA ultrasound images were acquired during normal ultrasound examination in hospital. AP diameter from	129 Native AAA datasets were gathered from one hospital in Copenhagen, Denmark. 91 of the exams met the inclusion criteria. All	At least 80% of all cases in which Philips AAA Model provides maximum AP diameter results that match standard of care	Result met the target successful rate.

Clinical testing	Test Method	Sample	Acceptance Criteria	Result
	2D ultrasound measurement, and from 3D ultrasound measurement with AAA model are compared.	patients age> 18 years old.	measurements to within ± 10%	
Post –EVAR AAA clinical evaluation	Post-EVAR AAA ultrasound images were acquired during normal ultrasound examination in hospital. AP diameter from 2D ultrasound measurement, and from 3D ultrasound measurement with AAA model are compared.	77 Post-EVAR AAA datasets were gathered from one hospital in Copenhagen, Denmark. 45 of the exams met the inclusion criteria. All patients age> 18 years old.	At least 80% of all cases in which Philips AAA Model provides maximum AP diameter results that match standard of care measurements to within ± 10%	Result met the target successful rate.

8. Sterilization

Not applicable. This is a software only device.

9. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed AAA Model meets the intended use. The differences between the subject device and predicate device do not raise new questions of safety and/or effectiveness. Therefore, the proposed AAA Model is substantially equivalent to the predicate QLAB Advanced Quantification Software applications in terms of intended use, technological characteristics, safety and effectiveness.