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

August 17, 2020

Re: K201352
Trade/Device Name: 3D Auto LAA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 21, 2020
Received: July 22, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201352

Device Name
3D Auto LAA

Indications for Use *(Describe)*
The 3D Auto LAA is a software application designed to view and quantify 3D image data acquired by Philips Ultrasound Systems for use in measuring the area, circumference, and diameter of a Left Atrial Appendage (LAA) orifice.

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 K201352

Philips 3D Auto LAA Cardiac Quantification Application

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
Senior Regulatory Affairs Specialist
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Phone: (908) 227-9423
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Secondary Contact: Hebe Sun
Senior Manager, Regulatory Affairs

Date Prepared May 20, 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: 3D Auto LAA

Common Name: 3D Auto LAA
Picture Archiving and Communications System (PACS)

Regulation Description:

Classification Description	21 CFR Section	Product Code
Picture Archiving and Communications System	892.2050	LLZ

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

The 3D Auto LAA is a software application designed to view and quantify 3D image data acquired by Philips Ultrasound Systems for use in measuring the area, circumference, and diameter of a Left Atrial Appendage (LAA) orifice.

4. Device Description

The purpose of this Traditional 510(k) Pre-market Notification is to introduce the new 3D Auto LAA cardiac quantification application for use on the Philips EPIQ and Affiniti Diagnostic Ultrasound systems, which were most recently cleared under K201012. The 3D Auto LAA application is compatible with 3D images generated via Philips Transesophageal Echocardiogram (TEE) transducers such as the X8-2t and X7-2t. The Philips 3D Auto LAA cardiac quantification application is a semi-automated application intended to provide measurements of the Left Atrial Appendage. The 3D Auto LAA application is designed to provide automatic and editable area, circumference, and diameter measurements of the Left Atrial Appendage (LAA) orifice. When the 3D Auto LAA application is launched, going through the workflow provides the clinician with a semi-automated preliminary border of the LAA in three planes based on greyscale intensity differentiation with some shape regularization.

5. Substantially Equivalent Devices

Primary Predicate Device

Philips QLAB Advanced Quantification Software System	K191647	December 20, 2019

6. Technological Comparison to Predicate Devices

The introduction of the new 3D Auto LAA cardiac quantification application has an equivalence intended use and similar technological characteristics as the legally marketed primary QLAB System predicate device with the distinction being that the 3D Auto LAA application is specific to LAA viewing and quantification. A comparison of the subject 3D Auto LAA application to the currently marketed predicate QLAB System device is provided in the table below:

Table 8-1: Comparison of The Subject Philips 3D Auto LAA Cardiac Quantification Application to the predicate Philips QLAB System (the 3DQ Q-App)

	Subject Device	Predicate Device	Explanation of Differences
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	None
Trade Name	3D Auto LAA	QLAB System	None
Feature	3D Auto LAA	3DQ	None
510(k) Number	Pending	K191647	None
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	The Regulation Number, Regulation Name, Classification, and Product Code are identical between the subject device and the primary predicate device.
Regulation Name	System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	System, Image processing, Radiological - Picture Archiving and Communications System (PACS)	
Classification	Class II	Class II	
Product Code(s)	LLZ	LLZ	
Indications for Use	The 3D Auto LAA is a software application designed to view and quantify 3D image data acquired by Philips Ultrasound Systems for use in measuring the area, circumference, and diameter of a Left Atrial Appendage (LAA) orifice.	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	The Indications for Use of the subject 3D Auto LAA application and the primary predicate QLAB System are equivalent with the underlying difference being that the 3D Auto LAA application specifically identifies the anatomical structure / region (the LAA) and the measurements that are reported to the end user (area, circumference, etc.).
System Components	Software only system	Software only system	The System Components of the subject 3D Auto LAA application and the QLAB System are identical as they both are software only systems.
Availability	3D Auto LAA application is available only on-cart for the Philips Ultrasound EPIQ and Affiniti Ultrasound Systems	The QLAB System 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 availability of the 3D Auto LAA and the QLAB System are similar in that both software systems are available on the Philips Diagnostic Ultrasound Systems as dedicated on-cart applications. However, the QLAB System offers the added freedom to be used

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		Subject Device	Predicate Device	Explanation of Differences
Manufacturer		Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	None
Trade Name		3D Auto LAA	QLAB System	None
Feature		3D Auto LAA	3DQ	None
				off-cart in variable capacities whereas the 3D Auto LAA application does not allow for this.
Software Design	Application Description	The 3D Auto LAA cardiac quantification application is a semi-automatic tool that is intended to assist the end user with LAA border detection and provide specific measurements for the orifice. This application is provided as an on-cart option only.	The 3DQ Q-App provides a manual way to view, slice, and display 3D volumes and measure distance and areas from MPR views to get biplane volume and ejection fraction in addition to mass calculations. QLAB Q-Apps are available both on and off-cart options.	The subject 3D Auto LAA application introduces a semi-automated workflow to provide the user with a dedicated tool for LAA quantification for on-cart use only. . The primary predicate QLAB 3DQ Q-App does also allow the user to measure and quantify several various cardiac structures but this is an all manual process
	Quantification Technology for Cardiac	Manual MPR alignment that results in semi-automated border generation of the LAA orifice and provides measurements based on preliminary border generated by algorithm. The border and the measurements can be further refined by the end user.	Manual border drawing / tracing ability in addition to manual MPR alignment and provides preliminary measurement estimates based on user defined border.	The subject 3D Auto LAA application introduces a semi-automatic border detection functionality for the LAA orifice while specifying the measurements specific to the LAA. The ability to align the MPRs based on the anatomical structure is a shared feature across both the primary and reference predicate devices.
	Contour Generation	LAA border is semi-autonomously generated following the MPR alignment by the end user by utilizing greyscale intensity differentiation with some shape regularization. The user can then modify the entire contour (utilizing the rotary knob) or an individual point(s) utilizing the trackball.	Contour is generated manually by the end user utilizing the trackball and if the contour needs modification, the end user must retrace the contour.	The 3D Auto LAA introduces a semi-automated workflow for the border generation as compared to both predicate devices. Similarly to the 3D Auto LAA application, the predicate devices both allow for the user to modify and adjust the MPRs to better fit the anatomy. However, the predicate devices the user must manually

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		Subject Device	Predicate Device	Explanation of Differences
Manufacturer		Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	None
Trade Name		3D Auto LAA	QLAB System	None
Feature		3D Auto LAA	3DQ	None
				draw / trace the contour utilizing the trackball.
	Measurements Parameters	✹LAA Area (mm^2) ✹LAA Circumference (mm) ✹LAA Max Diameter (mm) ✹LAA Minimum Diameter (mm)	✹Area (cm^2) ✹Circumference (cm) ✹Distance (cm) (can be utilized to draw a line and quantify both the max and min diameters)	The measurements provided by the 3D Auto LAA application are presented to the user as specific to the LAA orifice, however; the primary predicate and reference predicate devices are also capable of quantifying those measurement parameters as the 3D Auto LAA application.

7. Non-Clinical Testing

The proposed introduction of the subject Philips 3D Auto LAA cardiac quantification application was tested in accordance with Philips internal processes. Verification and software validation test data are provided to support the newest cardiac quantification application, the 3D Auto LAA application, relative to the currently marketed manual LAA tracing and measuring options.

Design Control activities to assure the safe and effective performance of the 3D Auto LAA application 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 Performance Validation Study for the proposed 3D Auto LAA clinical application.

Software Verification and Validation testing were used to support substantial equivalence of the new 3D Auto LAA cardiac quantification application (as part of the EPIQ / Affiniti System software release version 7.0) to the currently marketed manual LAA tracing and measuring options.

8. Clinical Testing

The subject Philips 3D Auto LAA cardiac quantification application 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 3D Auto LAA cardiac quantification application is substantially equivalent to the predicate device Philips QLAB System (K191647). Testing performed demonstrated that the proposed 3D Auto LAA application meets the defined requirements and performance claims.