



October 7, 2024

Philips Ultrasound LLC
Michael Chambers
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, WA 98021

Re: K240980

Trade/Device Name: EPIQ Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH, OBJ
Dated: April 10, 2024
Received: August 19, 2024

Dear Michael Chambers:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

 Yanna S. Kang -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K240980

Device Name

EPIQ Series Diagnostic Ultrasound System

Indications for Use (Describe)

The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

The clinical environments where EPIQ Series Diagnostic Ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

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 21 CFR § 807.92.

510(k) Number: K240980

Date Prepared: August 16, 2024

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	Mike Chambers Senior Regulatory Affairs Specialist 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA +1 (315) 262-7702
Secondary Contact	Erdit Gremi Director, Regulatory Affairs Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA +1 (617) 798-8092

II. Device

Proprietary Name	EPIQ Series Diagnostic Ultrasound System
Common Name	Diagnostic Ultrasound System and Transducers

Regulation Description	Classification Description	21 CFR §	Product Code
	Primary		
	System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
	Secondary		
	System, imaging, pulsed echo, ultrasonic	892.1560	IYO
	Transducer, ultrasonic, diagnostic	892.1570	ITX
	Automated Radiological Image Processing Software	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	OBJ	

Device Class	Class II
Review Panel	Radiology
Predicate Device	K233788; Philips EPIQ Series Diagnostic Ultrasound System
Reference Devices	K213544; TOMTEC-ARENA, TOMTEC Imaging Systems GmbH K200974; QLAB Advanced Quantification Software

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the 3D Auto TV (Tricuspid Valve) software application onto the EPIQ Series Diagnostic Ultrasound Systems.

The 3D Auto TV software enables semi-automated quantification of the tricuspid valve. At a high level, this is accomplished through automatically derived measurements from a segmented model of the tricuspid valve annulus formed by the software through model-based segmentation of the acquired ultrasound images.

The 3D Auto CFQ software provides semi-automated quantification of Mitral Regurgitation (MR) volume and peak flow rate based on 3D color flow images. This application uses a known fluid dynamic model of flow that is adapted to the acquired color information. This allows quantitative assessment of mitral valve leakage during systole. The derived result supports the assessment of mitral regurgitation volume and peak flow rate.

No hardware changes to the EPIQ systems are required when using the 3D Auto TV and 3D Auto CFQ, and existing, cleared Philips transducer(s) are used for the software applications.

The software applications are supported by all EPIQ models running software version 11.0 or higher including EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, EPIQ 5. The software applications are both associated with the cardiac adult indication.

IV. Intended Use and Indications for Use

EPIQ Intended Use

The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body.

EPIQ Indications for Use:

The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

The clinical environments where EPIQ Series Diagnostic ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Note: There are no changes to the EPIQ Ultrasound System Indications for Use due to the introduction of the 3D Auto TV or 3D Auto CFQ software applications. Both are associated with the Cardiac Adult indication.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the 3D Auto TV and 3D Auto CFQ software applications to the EPIQ Series Diagnostic Ultrasound System. The subject device is substantially equivalent to the predicate device (K233788).

The following tables provide an overview of the comparison of similarities and differences between the proposed device and the predicates. Details are provided in Attachment 005 of the submission.

Table 1: Comparison to Predicate for introduction of **3D Auto TV** onto EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto TV Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	TOMTEC-ARENA Feature: 4D CARDIO-VIEW K213544 Reference Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
Indications for Use	Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.	Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.	Quantification and reporting of cardiovascular, fetal, and abdominal structures and functions of patients with suspected disease to support the physician in the diagnosis.	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems	Identical to predicate
Intended Users	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Licensed medical practitioners or assistant medical technicians	Trained healthcare professionals	Identical to predicate

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto TV Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	TOMTEC-ARENA Feature: 4D CARDIO-VIEW K213544 Reference Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
Intended User Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Inside and outside of Hospitals, Clinics, and Physician's offices	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical to predicate
USA FDA Classification	Class II	Class II	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	QIH	QIH	Identical to predicate
Application Description	<p>The 3D Auto TV software solution is intended for use with the Philips EPIQ Diagnostic Ultrasound Systems. The software enables semi-automated quantification of the tricuspid valve. At a high level, this is accomplished through automatically derived measurements from a segmented model of the tricuspid valve annulus formed by the software through model-based segmentation of the acquired ultrasound images.</p>	<p>The predicate EPIQ Series Diagnostic Ultrasound System does not currently have a dedicated software application for quantification of the tricuspid valve annulus. The subject of this submission is to introduce the 3D Auto TV software onto the predicate device.</p>	<p>4D CARDIO-VIEW is an advanced analysis tool for 3D/4D echocardiography data. Anatomical structure visualization, volume measurements (LV and/or generic), and specified or manual measurements are possible for cardiac structures including, but not limited to, the tricuspid valve. Various tools are available for rendering that display 2- and 3-dimensional morphology and function for defined structures.</p>	<p>3D Auto MV is a semi-automated software application intended for the analysis of Mitral Valve (MV) anatomy and function. This application generates models of anatomical structures of interest such as the MV annulus, leaflets, and the closure line, which allows for quantification of pre- and post-operative valvular function and a comparison of morphology.</p>	<p>Similar to the reference device features.</p> <p>The functionality and workflow of the 3D Auto TV software is very similar to the 3D Auto MV tool, where measurement parameters are derived from models of the mitral valve (in the case of 3D Auto MV) and tricuspid valve (in the case of 3D Auto TV). Manual measurements are also able to be performed on both software applications.</p> <p>Comparing 3D Auto TV to 4D CARDIO-VIEW, both software have functionality for quantifying the tricuspid valve. The proposed 3D Auto TV allows for semi-automated quantification, where the reference device is fully manual. As we demonstrate high agreement in the measurement outputs on the same patients when quantified using the proposed 3D Auto TV software and the reference 4D CARDIO-VIEW application, there are no new questions raised of safety or effectiveness.</p>
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	No standard tricuspid valve (TV) quantification parameters included as part of the system.	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.	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.	Subject device uses identical method for contour generation as the reference device K200974. The only difference is the algorithm is trained on tricuspid valve images, where the reference

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto TV Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	TOMTEC-ARENA Feature: 4D CARDIO- VIEW K213544 Reference Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
	valve anatomical locations.				device was trained using mitral valve images.
Measurements Performed	<p>Semi-auto annulus results</p> <ul style="list-style-type: none"> • TV Ann Perimeter (3D) • TV Ann Perimeter (2D) • TV Ann Max Diam (2D) • TV Ann Min Diam (2D) • TV Ann Perimeter Derived Diam (2D) • TV Ann Height (3D) • TV Ann Area (2D) <p>Manual device results</p> <ul style="list-style-type: none"> • TV Ann AP Diam (2D) • TV Ann SL Diam (2D) • Subvalvular 5 Plane SL Diam • Subvalvular 5 Plane AP Diam • Supralvular C-Shaped Perimeter • Supralvular AV - AoCenter Diam 	No standard tricuspid valve (TV) quantification parameters included as part of the system.	<p>TAVR results</p> <ul style="list-style-type: none"> • Ann-Ost left diam • Ann-Ost right diam • Annulus Area • Annulus dmin • Annulus dmax • Ao Ring diam • Ao SV diam • Ao STJ diam <p>Volume results (not related to TV quantification)</p> <ul style="list-style-type: none"> • EDV • EF • ESV • GenVol • Mass • SV 	<p>Standard MV Parameters</p> <ul style="list-style-type: none"> • 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 (cm3) • Coaptation Depth (mm) • Tenting Area (cm2) • Angle AAO-AP (degrees) • Maximum Prolapse Height (mm) • Maximum Open Coaptation Gap (mm) • Maximum Open Coaptation Width (mm) • Anterior Leaflet Area (cm2) • Posterior Leaflet Area (cm2) • Distal Anterior Leaflet Angle (degrees) • Posterior Leaflet Angle (degrees) • Anterior Leaflet Length (cm) • Posterior Leaflet Length (cm) • C-Shaped Annulus (cm) <p>2D MV Parameters</p> <ul style="list-style-type: none"> • D-Shaped Annulus Area (cm2) • Annulus Area (cm2) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) <p>3D MV Parameters</p> <ul style="list-style-type: none"> • Saddle Shaped Annulus Area (cm2) • Saddle Shaped Annulus Perimeter (cm) • Total Open Coaptation Area (cm2) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) 	<p>Similar. The proposed 3D Auto TV software allows very similar semi-automated measurements as the reference software application 3D Auto MV, only applied to the tricuspid valve.</p> <p>The proposed 3D Auto TV software adds additional TV annulus and device measurements from those available in 4D CARDIO-VIEW to further define the tricuspid valve anatomy.</p> <p>Both the proposed 3D Auto TV and the reference 4D CARDIO-VIEW software allow manual, free-form measurements of the tricuspid valve.</p>

Table 2: Comparison to Predicate for introduction of **3D Auto CFQ** onto EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto CFQ Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
Indications for Use	Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.	Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.	QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems	Identical to predicate
Intended Users	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Trained healthcare professionals	Identical
Intended User Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical
USA FDA Classification	Class II	Class II	Class II	Identical
Primary Product Code	IYN	IYN	QIH	Identical to predicate
Application Description	3D Auto CFQ is a new semi-automated quantification software which will be introduced on the EPIQ Ultrasound Systems from software version VM11.0. The application provides semi-automated quantification of Mitral Regurgitation (MR) volume and peak flow rate by analyzing 3D color flow images acquired during transesophageal echocardiography (TEE) examinations.	The Proximal Isovelocity Surface Area (PISA) methodology can be used currently on the predicate device to quantify valvular regurgitation. The technique utilizes 2D/Color and Doppler images to allow the user to make simple, manual measurements in a cascading fashion to allow calculation of peak flow rate and volumetric regurgitation.	3D Auto MV is a semi-automated software application intended for the analysis of Mitral Valve (MV) anatomy and function. This application generates models of anatomical structures of interest such as the MV annulus, leaflets, and the closure line, which allows for quantification of pre- and post-operative valvular function and a comparison of morphology.	Similar. The predicate device facilitates the quantification of mitral regurgitation volume and peak flow rate through a group of measurements which are performed in a cascading fashion manually by the user according to the Proximal Isovelocity Surface Area (PISA) methodology. The proposed 3D Auto CFQ software application allows the users to quantify the same measurements for mitral regurgitation volume and peak flow rate but in a semi-automated workflow.

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto CFQ Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
				The reference device does not contain functionality for quantification of mitral regurgitation.
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.	No standard contour generation technology for the mitral valve, outside of 3D Auto MV, included as part of the system.	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.	Subject device uses identical method for contour generation as the reference device K200974
Quantification Technology for Mitral Regurgitation	<p>The 3D Auto CFQ algorithm quantifies mitral regurgitation volume and flow rate from acquired 3D color flow images. The greyscale information from these images is used to generate a 3D model of the mitral valve, which is used as an input along with the 3D color data into the 3D Auto CFQ flow algorithm. The 3D Auto CFQ algorithm uses a fluid dynamic model of an incompressible fluid (blood) traveling through an irregular-shaped (i.e., nonround) orifice. In its initial step, the algorithm generates a hypothetical model of true blood flow velocities in the proximal convergence zone based on all measured Doppler velocities and the underlying fluid dynamics model. The true velocity model is then converted into the corresponding apparent Doppler velocity model ("synthetic apparent velocities") using ultrasound physics (projection along the axial dimension). These synthetic velocities are subsequently compared to the acquired velocities in the Color Flow (CF) data set. Based on the outcome of this comparison, the model is updated and reiterated to get the best fit between the acquired velocities and the generated model. 3D Auto CFQ determines the resulting regurgitant flow rate for this frame. This process is repeated for each frame included in the analysis, which in most cases includes the entire systolic cycle. In each frame, the size and shape of the regurgitant orifice is not assumed but is generated by this iterative loop between the model and the CF data.</p>	<p>The PISA methodology uses sequential acquisitions and manual measurements, which are manually performed by the user:</p> <ul style="list-style-type: none"> • MR Alias Velocity (from the 2D/Color) • MR Radius (from the 2D/Color) • MR Vmax (from the continuous wave doppler) • MR VTI (from the continuous wave doppler) <p>The outputs of these measurements go into the equations for the derived measurements including:</p> <ul style="list-style-type: none"> • Mitral Regurgitant (MR) Flow Rate • MR Effective Regurgitant Orifice (ERO) • MR Volume 	N/A – does not contain technology for mitral regurgitation quantification	<p>Similar. The predicate device utilizes the PISA methodology for quantifying MR volume and flow rate. This methodology utilizes sequential measurements performed by the user and is based on assumptions including there being a single, round, constant flow orifice during the entire systole.</p> <p>3D Auto CFQ operates using 3D color to address the spatial complexities seen in mitral regurgitation and was developed to evaluate the regurgitant flow at every frame in systole, where the PISA methodology only assesses one frame during systole and assumes this frame applies across systole.</p> <p>The proposed 3D Auto CFQ software application allows the users to quantify the same measurements for mitral regurgitation volume and peak flow rate as PISA. The dynamic flow algorithm is the new technology introduced in this submission. Everything leading up to the calculations by the dynamic flow model are existing and cleared, including the transducer and imaging modes (X8-2t transducer; 3D Zoom, Full Volume 3D, or Live 3D; K163120), and software for mitral valve model generation (reference device K200974). The dynamic flow model of the 3D Auto CFQ software application uses these as inputs to arrive at the outputs of mitral regurgitation volume and peak flow rate. These outputs are the same as in the predicate, only the method to arrive at the</p>

Feature	EPIQ Series Diagnostic Ultrasound System Feature: 3D Auto CFQ Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	QLAB Advanced Quantification Software Feature: 3D Auto MV K200974 Reference Device	Comparison
				measurements differs in the subject device.
Compatible transducers	<p>3D9-3V, C5-1, C8-5, C9-2, C10-3V, C10-4ec, D2cwc, D2tcd, D5cwc, eL18-4, eL18-4 EMT, L12-3, L12-3 ERGO, L12-5 50, L15-7io, L18-5, mC7-2, mC12-3, mL26-8, S5-1, S7-3t, S8-3, S8-3t, S9-2, S12-4, V6-2, V9-2, VL12-5, X5-1, X5-1c, X6-1, X7-2, X7-2t, X8-2t, X11-4t, XL14-3</p> <p>The 3D Auto CFQ software application can analyze transesophageal echocardiography (TEE) images acquired by the cleared X8-2t transducer (K163120), which is already commercially available and compatible with the EPIQ Ultrasound System.</p>	<p>3D9-3V, C5-1, C8-5, C9-2, C10-3V, C10-4ec, D2cwc, D2tcd, D5cwc, eL18-4, eL18-4 EMT, L12-3, L12-3 ERGO, L12-5 50, L15-7io, L18-5, mC7-2, mC12-3, mL26-8, S5-1, S7-3t, S8-3, S8-3t, S9-2, S12-4, V6-2, V9-2, VL12-5, X5-1, X5-1c, X6-1, X7-2, X7-2t, X8-2t, X11-4t, XL14-3</p>	<p>The 3D Auto MV software application is compatible with the following transducers: X7-2t, X8-2t, X11-4t</p>	<p>Identical. There are no new transducers introduced in this 510(k).</p> <p>The 3D Auto CFQ software application can analyze transesophageal echocardiography (TEE) images acquired by the cleared X8-2t transducer (K163120), which is already commercially available and compatible with the EPIQ Ultrasound System.</p> <p>There are no impacts to the indications for use or intended use of the X8-2t transducer when used for the purposes of acquiring images for analysis by the 3D Auto CFQ software application. The 3D Auto CFQ software application requires images to be acquired in either 3D Zoom, Full Volume 3D, or Live 3D imaging modes. There are no changes to these existing transducer imaging modes.</p>
Measurements Performed	<p>Semi-automated measurements performed by the 3D Auto CFQ software application:</p> <p>Mitral regurgitation (MR) volume [mL]; Peak flow rate [mL/s]</p>	<p>Derived measurements which the user can obtain through the PISA methodology include:</p> <p>Mitral regurgitation (MR) volume [mL]; Peak flow rate [mL/s]</p>	<p>Standard MV Parameters</p> <ul style="list-style-type: none"> • 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 (cm3) • Coaptation Depth (mm) • Tenting Area (cm2) • Angle AAo-AP (degrees) • Maximum Prolapse Height (mm) • Maximum Open Coaptation Gap (mm) • Maximum Open Coaptation Width (mm) • Anterior Leaflet Area (cm2) • Posterior Leaflet Area (cm2) • Distal Anterior Leaflet Angle (degrees) • Posterior Leaflet Angle (degrees) • Anterior Leaflet Length (cm) • Posterior Leaflet Length (cm) • C-Shaped Annulus (cm) <p>2D MV Parameters</p>	<p>Similar. The measurements performed by the proposed 3D Auto CFQ software application can also be obtained by a user on the predicate device.</p> <p>Substantiation of the performance of the 3D Auto CFQ software's regurgitant volume output was performed by comparison to cardiac magnetic resonance imaging (CMR) images with acceptance criteria of agreement within the limits of agreement. While the PISA methodology is a widely accepted method for mitral regurgitation quantification and is a recommended method by the American Society of Echocardiography, the outputs from 3D Auto CFQ were compared to those from CMR (as opposed to PISA) as the former is considered a gold standard for mitral regurgitation quantification.</p> <p>Acceptance criteria for 3D Auto CFQ was based on</p>

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			<ul style="list-style-type: none"> • D-Shaped Annulus Area (cm²) • Annulus Area (cm²) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) <p>3D MV Parameters</p> <ul style="list-style-type: none"> • Saddle Shaped Annulus Area (cm²) • Saddle Shaped Annulus Perimeter (cm) • Total Open Coaptation Area (cm²) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) 	<p>agreement with CMR being within predefined maximum limits of agreement.</p> <p>In addition to regurgitant volume, the peak flow rate output of 3D Auto CFQ was validated in comparison to manual PISA method, where the correlation was very high.</p> <p>The reference device K200974 facilitates anatomical measurements of the mitral valve from the generated model of the mitral valve but does not perform measurements for quantifying mitral regurgitation.</p>

VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System, including 3D Auto TV and 3D Auto CFQ software applications, and compatible transducers are all Track 3 Devices and comply with the referenced standards as well as the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, issued in February 2023.

VII. Nonclinical Performance Data

The proposed modification of the EPIQ Series Diagnostic Ultrasound Systems was tested in accordance with Philips internal procedures. Philips Ultrasound tested the subject devices per the following standards to ensure the continued safe and effective performance:

- IEC 62304 Medical device software – Software life cycle processes, 2006 + A 2015
- ISO 14971 Medical devices- Application of risk management to medical devices, 2019

Non-clinical verification testing was conducted to address the change and performance test data were provided to support the introduction of the subject 3D Auto TV and 3D Auto CFQ software applications. The activities to assure the safe and effective performance of the software revision included, but are not limited to, the following:

- Requirements Review
- Risk Analysis and Management Review
- Product Specification Review
- Design Reviews

Non-clinical testing also included the Performance Validation Study for the proposed 3D Auto TV and 3D Auto CFQ software applications.

For 3D Auto TV, a study was conducted to evaluate the automation performance of the 3D Auto TV software, where transthoracic and transesophageal echocardiography (TTE, TEE) cardiac clips were used for TV annulus measurements by 3 clinical experts (reviewers) with the use of 3D Auto TV software and the results compared to manual measurements by the same reviewers performed within 4D Cardio-View application (K213544), used as a ground truth for the study. Subjects whose clips

contributed to the study represented a broad range of demographics, body habitus, and their severity of tricuspid regurgitation were representative of the intended population. The results of the primary endpoint analysis demonstrated high agreement of the automated performance of the 3D Auto TV software with the 4D Cardio-View software (ground truth). Confidence intervals for the limits of agreement were within the acceptance criteria $\pm 46\%$ and $\pm 52\%$ for annulus size and annulus shape, respectively, within TEE and TTE arms. Bias was also evaluated for automation performance, where relative bias based on inter-observer variability was met, specifically within $\pm 17.37\%$ for distance (size) and $\pm 23.68\%$ for circumference (shape). The accuracy and precision of the underlying measurement primitives were also evaluated through use of in silico phantoms with known dimensions. Mean relative error of the measurement primitives on the in-silico phantoms were within $\pm 1\%$, with limits of agreement within acceptance criteria of $\pm 5\%$.

For 3D Auto CFQ, a study was conducted to evaluate the performance of the 3D Auto CFQ software. The results were compared to cardiac magnetic resonance imaging (CMR) regurgitant volume (RVol), used as a ground truth for the study. This study produced limits of agreement (LoA) of -49.29 (lower LoA) and 25.09 (upper LoA) and associated confidence intervals: lower end of 95% LoA (-58.37,-40.20) and upper end of 95% LoA (16.01,34.18). The acceptance criteria set for the study was defined as maximum allowable difference (Δ) of 61.6ml. Based on the results of the study, the lower end of the 95% CI for LoA was -58.37 and the upper end of the 95% CI for LoA was 34.18, therefore the primary endpoint acceptance criteria for maximum allowable difference were met. In addition, bias was assessed where the acceptance criteria for mean difference (bias) within $\pm 19.2\text{ml}$ was met. Further, the peak regurgitant flow output from 3D Auto CFQ was also validated against 2D PISA methodology on the same subjects. For both fully-automated and semi-automated 3D Auto CFQ, the upper and lower bounds of the 95% confidence interval for Pearson's correlation exceeded the acceptance criteria of > 0.8 when compared to 2D PISA. All acceptance criteria for the studies were met, and the results of the study demonstrated clinically reasonable, relevant, meaningful performance of the 3D Auto CFQ software supporting clinicians' assessment of mitral valve regurgitant volume during cardiac TEE exam.

Since these are software-only changes and no new hardware was added, no acoustic output, cleaning and disinfectant, thermal, electrical, electromagnetic, and mechanical safety testing were required. Biocompatibility testing is not needed for the subject EPIQ Series Diagnostic Ultrasound Systems with 3D Auto TV and 3D Auto CFQ. The transducer patient contact materials and manufacturing processes are not impacted by the release of the subject EPIQ Series Diagnostic Ultrasound Systems with 3D Auto TV and 3D Auto CFQ.

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ Series Diagnostic Ultrasound Systems with 3D Auto TV and 3D Auto CFQ software applications.

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

Results of the testing shows that the proposed subject device meets its intended use support a determination that the proposed subject device does not raise new questions of safety or effectiveness.

Therefore, the subject device is substantially equivalent to the predicate device in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.