Philips Ultrasound LLC
Petra Galgoczy
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021

February 10, 2025

Re: K241659
Trade/Device Name: Ultrasound Workspace (UWS 6.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ, IYN
Dated: June 10, 2024
Received: January 16, 2025

Dear Petra Galgoczy:

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,

Jessica Lamb, PhD
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241659

Device Name

Ultrasound Workspace (UWS 6.0)

Indications for Use *(Describe)*

Indications for use of the product are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.

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: _____K241659_____

Date Prepared: November 18, 2024

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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II. Device

Proprietary Name

Ultrasound Workspace (UWS 6.0)

Common Name

Picture archiving and communications system

Regulation Description

Classification Description	21 CFR §	Product Code
Primary		
Automated Radiological Image Processing Software	892.2050	QIH
Secondary		
Medical image management and processing system	892.2050	LLZ
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN

Device Class

Class II

Review Panel

Radiology

Predicate Device

K213544; TOMTEC-ARENA (TTA2.50)

Reference Devices

K240850; EPIQ Series Diagnostic Ultrasound System with SWM
K202216, EPIQ Series Diagnostic Ultrasound System with ICE/Pro ICE

III. Device Description

The purpose of this Traditional 510(k) Pre-market Notification is to introduce the SWM, 3D Auto TV and 3D Auto CFQ software applications as well as compatibility of VeriSight ICE / Pro ICE Probe data with the subject device Ultrasound Workspace Version 6.0.

The semi-automated Segmental Wall Motion feature (SWM) evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. It performs border detection and tracking to identify each of the LV segments, provides segmental wall motion scores for each segments of the LV by using machine learning algorithms and calculates an overall wall motion score index (WMSI) as the average of the segmental scores.

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.

3D Auto CFQ 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.

Data Compatibility of the VeriSight ICE / Pro ICE Probe, transducers cleared for the EPIQ Series Diagnostic Ultrasound System (K202216), will be introduced for Ultrasound Workspace 6.0.

General software architecture of the previously cleared version TOMTEC-ARENA remains unchanged. Two new clinical application packages will be introduced with UWS6.0: 3D Auto TV and 3D Auto CFQ. An existing feature AutoStrain Left Ventricle (AutoStrain LV) gains additional functionality by integration of Segmental Wall Motion (SWM) feature. The module using AutoStrain LV together with SWM is named 2D Auto LV.

IV. Intended Use and Indications for Use

Ultrasound Workspace Intended Use

Ultrasound Workspace is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.

Ultrasound Workspace Indications for Use

Indications for use of Ultrasound Workspace are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.

Intended Use Environments

Intended Use Environments are inside and outside of Hospitals, Clinics, and Physician´s offices.

Ultrasound Workspace is intended to be used only by licensed medical practitioners or assistant medical technicians.

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 licensed medical practitioners or assistant medical technicians 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 Ultrasound Workspace for Intended Use / Indications for Use due to the introduction of the SWM, 3D Auto TV and 3D Auto CFQ feature and usage of data derived from VeriSight ICE / Pro ICE data. SWM, 3D Auto TV and 3D Auto CFQ software is associated with the Cardiac Adult indication.

V. Comparison of Technological Characteristics with the Predicate and Reference Devices

The purpose of this Traditional 510(k) Pre-market Notification is to introduce the SWM, 3D Auto TV and 3D Auto CFQ software applications and compatibility of VeriSight ICE / Pro ICE Probe data with the Ultrasound Workspace Version 6.0 software package. The subject device is substantially equivalent to the predicate device (K213544).

The following tables provide an overview of the comparison of similarities and differences between the proposed device, the predicate and reference devices.

Table 1: Comparison to Predicate and Reference Device for introduction of **SWM** onto UWS6.0

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 Predicate Device	EPIQ Series Diagnostic Ultrasound System Reference Device	Comparison
K-number	Not available	K213544	K240850	Subject of this submission is UWS6.0
Intended Use	**The product** is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities. The product is not intended to be used for reading of mammography images.	**TOMTEC-ARENA** software is a clinical software package designed for review, quantification and reporting of structures and function based on multi-dimensional digital medical data acquired with different modalities.TOMTEC-ARENA is not intended to be used for reading of mammography images.	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.	Intended Use/Indications for use of predicate and subject device are identical (unchanged) - except of the product name (**bolded**). Intended Use/Indications for use of reference device and subject device are similar and considered equivalent (specifically if compared for the clinical use case/workflow of the subject feature).
Indications for Use	Indications for use **of the product** are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physician in the diagnosis.	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		
Intended Users	**The product** is intended to be used only by	**TOMTEC-ARENA software** is intended to be	The product is intended to be used only by licensed	Identical for predicate and subject device -except of

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 Predicate Device	EPIQ Series Diagnostic Ultrasound System Reference Device	Comparison
	licensed medical practitioners or assistant medical technicians.	used only by licensed medical practitioners or assistant medical technicians.	medical practitioners or assistant medical technicians.	the product name (**bolded**). Intended Users of reference device and subject device are similar and considered equivalent
Intended User Environment	Intended Use Environments are inside and outside of Hospitals, Clinics, and Physician´s offices.	Intended Use Environments are inside and outside of Hospitals, Clinics, and Physician´s offices.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical to predicate device. Difference to reference device is due to the fact that subject and predicate devices are software only, whereas reference device includes the ultrasound device.
USA FDA Classification	Class II	Class II	Class II	Identical
Primary Product Code	QIH	QIH	IYN	Identical to predicate device
Primary Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.1550	Identical to predicate device
Primary Regulation Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	System, Imaging, Pulsed Doppler, Ultrasonic	Identical to predicate device
Secondary Product Codes	LLZ IYN	LLZ	ITX IYO OBJ QIH	IYN is newly introduced with this submission
Secondary Regulation Number	21 CFR 892.2050 21 CFR 892.1550	21 CFR 892.2050	21 CFR 892.1570 21 CFR 892.1560 21 CFR 870.1200	Identical to predicate device.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 Predicate Device	EPIQ Series Diagnostic Ultrasound System Reference Device	Comparison
			21 CFR 892.2050	IYN is newly introduced with this submission
Secondary Regulation Name	System, Image Processing, Radiological System, Imaging, Pulsed Doppler, Ultrasonic	System, Image Processing, Radiological	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Identical to predicate device IYN is newly introduced with this submission
Application Description	The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. Note: Per FDA Guidance Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions, the SWM software is a semi-automated quantitative imaging algorithm, as users are generally expected to review and concur with the initialization and generated results. The	The predicate TOMTEC-ARENA does not currently have a dedicated software application containing the functionality introduced in the subject submission for (semi-) automated segmental wall motion evaluation of the left ventricle (LV).	Smart View Select is an automated software feature that assists the user in selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic (TTE) examination. The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. Note: Per FDA Guidance Technical Performance Assessment of	SWM functionality is missing in the predicate device. This feature is newly introduced with this submission. SWM in the subject and reference device is identical. In both cases SWM has been integrated in the existing feature AutoStrain LV. The module using AutoStrain LV together with SWM is named 2D Auto LV. Note: The Smart View Select feature described for the reference device is

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 Predicate Device	EPIQ Series Diagnostic Ultrasound System Reference Device	Comparison
	users can also edit algorithm generated segmental wall motion scores for individual segments based on their clinical expertise.		Quantitative Imaging in Radiological Device Premarket Submissions, the SWM software is a semi-automated quantitative imaging algorithm, as users are generally expected to review and concur with the initialization and generated results. The users can also edit algorithm generated segmental wall motion scores for individual segments based on their clinical expertise.	not included in the subject device UWS6.0.
SWM scoring adjustment	Users manually edit scores using a drop-down selection	Not applicable – does not contain functionality for segmental wall motion	Users manually edit scores using a drop-down selection	Identical to reference device
Introduction of segmental wall motion scores / overall wall motion score index (WMSI)	Segmental wall motion scores are indicated for 17 segments of the left ventricle. Overall wall motion score index (WMSI) is calculated.	Not applicable – does not contain functionality for segmental wall motion	Segmental wall motion scores are indicated for 17 segments of the left ventricle. Overall wall motion score index (WMSI) is calculated.	Identical to reference device. Wall motion scores are an additional value for evaluating the segmental (regional) function of the left ventricle (LV) using TTE echo examinations in adults.

Table 2: Comparison to Predicate for Introduction of **3D Auto TV** onto UWS6.0
For Indications for Use, Intended Use, Product Code Information, Classification please refer to Table 1.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
K-number	Not available	K213544	Subject of this submission is UWS6.0
Application Description 3D Auto TV	**3D Auto TV** software enables semi-automated quantification of the tricuspid valve during transesophageal echocardiography (TEE) and transthoracic echocardiography (TTE) examinations. It applies artificial intelligence for model based segmentation. 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.	**3D Auto MV** (formerly named *4D MV-ASSESSMENT*) 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. **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.	Similar to the predicate device features. 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. Comparing 3D Auto TV to **4D CARDIO-VIEW**, both software have functionality for quantifying the tricuspid valve. The proposed 3D Auto TV allows 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 (REF #4), there are no new questions raised of safety or effectiveness. The subject of this submission is introduction of semi-automated quantification via 3D Auto TV of UWS6.0.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
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 tricuspid valve anatomical locations.	**3D Auto MV:** 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. **4D CARDIO-VIEW**: 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.	Subject device uses identical method for contour generation as the **3D Auto MV** application of the predicate device. The only difference is the algorithm is trained on tricuspid valve images, where the predicate device was trained using mitral valve images
Measurements Performed	**Semi-auto annulus results** • 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) **Manual device results** • TV Ann AP Diam (2D) • TV Ann SL Diam (2D) • Subvalvular 5 Plane SL Diam • Subvalvular 5 Plane AP Diam • Supravalvular C-Shaped Perimeter • Supravalvular AV - AoCenter Diam	**3D Auto MV:** **Standard MV Parameters** • 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)	Similar. The proposed 3D Auto TV software enables a subset of very similar semi-automated measurements as the predicated software application **3D Auto MV**, only for the tricuspid annulus. 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. Both the proposed 3D Auto TV and the predicate 4D CARDIO-VIEW software allow manual, free-form measurements of the valve.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
		• C-Shaped Annulus (cm) **2D MV Parameters** • D-Shaped Annulus Area (cm2) • Annulus Area (cm2) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) **3D MV Parameters** • 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) **4D CARDIO-VIEW**: **TAVR results** • Ann-Ost left diam • Ann-Ost right diam • Annulus Area • Annulus dmin • Annulus dmax • Ao Ring diam • Ao SV diam • Ao STJ diam **Volume results (not related to TV quantification)** • EDV • EF • ESV • GenVol • Mass • SV	

Table 3: Comparison to Predicate for Introduction of **3D Auto CFQ** onto UWS6.0
For Indications for Use, Intended Use, Product Code Information, Classification please refer to Table 1.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
K-number	Not available	K213544	Subject of this submission is UWS6.0
Application Description 3D Auto CFQ	The 3D Auto CFQ is a new artificial intelligence software which will be introduced on the Ultrasound Workspace Software system starting with Version 6.0. The application provides semi-automated quantification of Mitral Regurgitation (MR) volume and peak flow rate based on 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. **3D Auto MV** feature of the predicate 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.	**PISA**: No standard contour generation technology for the mitral valve, outside of 3D Auto MV, included as part of the system. **3D Auto MV**: 3D surface model is created semi-automatically using machine learning	Subject device uses identical method for contour generation as the **3D Auto MV** feature of the predicate device.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
		algorithm without user interaction. User is able to edit, accept, or reject the initial landmark proposals of the mitral valve anatomical locations.	
Quantification Technology for Mitral Regurgitation	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	**PISA:** The PISA methodology uses sequential acquisitions and manual measurements, which are manually performed by the user: - 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) The outputs of these measurements go into the equations for the derived measurements including: - Mitral Regurgitant (MR) Flow Rate - MR Effective Regurgitant Orifice (ERO) - MR Volume **3D Auto MV:** N/A – does not contain technology for mitral regurgitation quantification	Similar. The **PISA** methodology of the predicate device – used for quantifying MR volume and flow rate - 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. **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. 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. Mitral valve model generation is identical to the **3D Auto MV** feature of the predicate device. The dynamic flow model of the 3D Auto CFQ software application uses this as input to arrive at the outputs of mitral regurgitation volume and peak flow rate. These outputs are

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
	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.		the same as in the predicate, only the method to arrive at the measurements differs in the subject device.
Measurements Performed	Semi-automated measurements performed by the 3D Auto CFQ software application: Mitral regurgitation (MR) volume [mL]; Peak flow rate [mL/s]	**PISA:** Derived measurements which the user can obtain through the PISA methodology include: Mitral regurgitation (MR) volume [mL]; Peak flow rate [mL/s] **3D Auto MV:** **Standard MV Parameters** • 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)	Similar. The measurements performed by the proposed 3D Auto CFQ software application can also be obtained by a user on the predicate device using the **PISA** methodology. Substantiation of the performance of the 3D Auto CFQ software's regurgitant volume output was performed by comparison to cardiac magnetic imaging with (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. Acceptance criteria for 3D Auto CFQ was based on agreement with CMR being within predefined maximum limits of agreement.

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 - K213544 Predicate Device	Comparison
		• C-Shaped Annulus (cm) **2D MV Parameters** • D-Shaped Annulus Area (cm2) • Annulus Area (cm2) • Anterior Closure Line Length (cm) • Posterior Closure Line Length (cm) **3D MV Parameters** • 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)	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. **3D Auto MV** feature of the predicate device facilitates anatomical measurements of the mitral valve from the generated model of the mitral valve but does not perform measurements for quantifying mitral regurgitation.

Table 4: Comparison to Predicate and Reference Device for Compatibility to **VeriSight ICE / Pro ICE** Probe on UWS6.0

Feature	Ultrasound Workspace Version 6.0 (UWS6.0) Proposed Device	TOMTEC-ARENA TTA2.50 Predicate Device	EPIQ Series Diagnostic Ultrasound System Reference Device	Comparison
K-number	Not available	K213544	K202216	Subject of this submission is UWS6.0
Transducer Clinical Application / cleared compatibility	VeriSight ICE / Pro ICE (Proposed Transducer) TEE (transesophageal) transducer. Intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The VeriSight ICE catheter provides 2D ultrasound imaging capabilities, while the VeriSight Pro ICE catheter provides 2D and/or 3D ultrasound imaging capabilities.	N/A, compatibility to VeriSight ICE / Pro ICE has not been shown.	VeriSight ICE / Pro ICE was introduced on EPIQ via K202216. TEE (transesophageal) transducer. Intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The VeriSight ICE catheter provides 2D ultrasound imaging capabilities, while the VeriSight Pro ICE catheter provides 2D and/or 3D ultrasound imaging capabilities.	Identical to reference device.
Data Compatibility	Compatibility to UWS6.0 is subject of this submission.	N/A, for TTA2 compatibility for VeriSight ICE / Pro ICE has not been shown.	VeriSight ICE / Pro ICE was introduced on EPIQ via K202216.	Identical to reference device.

VI. Nonclinical Performance Data

The proposed modification of Ultrasound Workspace (UWS6.0) 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

The approach taken by Philips Ultrasound is in alignment with the following FDA guidance documents:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (2023)
- Content of Premarket Submissions for Device Software Functions (2023)
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions (2022)
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (2002)

Non-clinical verification testing was conducted to address the change and performance test data were provided to support the introduction of the subject SWM, 3D Auto TV and 3D Auto CFQ software feature and the VeriSight ICE / Pro ICE Probe compatibility. 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

Completion of all verification activities demonstrated that the subject device meets all design and performance requirements. Verification activities performed confirmed that the differences in the design did not adversely affect the safety and effectiveness of the subject device.

Non-clinical testing also included performance validation of the proposed SWM, 3D Auto TV and 3D Auto CFQ software applications:

Performance Data for Segmental Wall Motion (SWM)
A retrospective data analysis study was conducted to assess the use of Segmental Wall Motion (SWM), a machine learning- based feature in quantification of Wall Motion Score Index (WMSI) in transthoracic (TTE) ultrasound clips obtained from subjects referred for clinical TTE exam. The study evaluated the performance of the integrated (subject) SWM algorithm compared to LVivo SWM (DiA Imaging Analysis) application (ground truth) in the quantification of WMSI for the same subjects' exams.
A review of published literature within the cardiac assessment space and previous regulatory submissions (compare K240850) informed the acceptance criteria for the study to be defined as Lower Confidence Bound for the Pearson's correlation coefficient to be >0.8 for each endpoint. Acceptance criteria were defined prior to study execution. The results showed a very strong correlation to the LVivo application for WMSI output (Pearsons's correlation coefficient of 0.957 (95%CI 0.933, 0.972), thereby meeting the predefined acceptance criteria for the study.

The 2D Auto LV application, including the Segmental Wall Scoring on Ultrasound Workspace, is found

to be safe and effective to use through a summative evaluation. 16 target users completed the critical tasks of saving desired measurements with a success rate of 97.7%. Two steps comprise the critical task: 'Save Measurements' and 'Exclude Measurements'. These steps were evaluated 44 times, with only one failure by one participant during the 'Save Measurements' critical task. But the failure is not safety related, since the participant didn't save a desired result instead of saving an undesired result.

Performance Data for 3D Auto TV

For 3D Auto TV, A study was conducted to evaluate the performance of the 3D Auto TV software, where transesophageal echocardiography (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, 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 3D Auto TV software with the 4D Cardio-View software (ground truth). Confidence intervals for the limits of agreement were within the acceptance criteria ± 46% and ± 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 +/- 17.37% for distance (size) and +/- 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 +/- 1%, with limits of agreement within acceptance criteria of +/- 5%.

Performance Data for 3D Auto CFQ

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 61.6 ml. 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 +/- 19.2ml 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 the subject device is software only, no acoustic output, cleaning and disinfectant, thermal, electrical, electromagnetic, mechanical safety and biocompatibility testing were required.

VII. Clinical Data

There was no clinical investigation needed for this premarket submission of the Ultrasound Workspace Version 6.0 with SWM, 3D Auto TV and 3D Auto CFQ features, also addition of data compatibility of the new probes did not trigger clinical investigation.

VIII. Sterilization

Not applicable. Ultrasound Workspace is a software-only device.

IX. Conclusion

During the testing of the new features, all pre-determined acceptance criteria were met. Results of these tests show 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.