February 6, 2025

Philips Ultrasound LLC
Deval Patel
Principal Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021

Re: K243794
Trade/Device Name: EPIQ Series Diagnostic Ultrasound System; Affiniti 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, OBJ, QIH
Dated: December 10, 2024
Received: December 10, 2024

Dear Deval Patel:

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

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)*

k243794

Device Name

EPIQ Series Diagnostic Ultrasound System
Affiniti Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

EPIQ:

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.

Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode , Power Doppler and Harmonic Imaging.

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.

Affiniti:

The intended use of Affiniti Series Diagnostic Ultrasound Systems 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), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode , Power Doppler and Harmonic Imaging.

The clinical environments where the Affiniti diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

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.

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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: K243794

Date Prepared: October 10, 2024

Date of Revision: February 5, 2025

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
22100 Bothell Everett Hwy
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II. Device

Proprietary Name

EPIQ Series Diagnostic Ultrasound System
Affiniti 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
Medical image management and processing system	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	OBJ

Device Class

Class II

Review Panel

Radiology

Predicate Device

K240850; Philips EPIQ Series Diagnostic Ultrasound System and Philips Affiniti Series Diagnostic Ultrasound System

Predicate 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
Medical image management and processing system	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	OBJ

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the change in AutoMeasure V3 software application onto the EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound Systems.

Philips AutoMeasure feature provides the end user semi-automated 2D, Doppler and M-mode measurements with an adult cardiology transthoracic transducer and acquisitions that includes an electrocardiogram (ECG). The Auto Measure feature is designed to provide semi-automated and editable measures during an echocardiography. When Auto Measure is enabled, the healthcare professional performs an echocardiography with a workflow that provides the user with a semiautomated measurement that can be edited, accepted, or rejected. AutoMeasure is available in the Adult Echo analysis application for acquisitions with ECG. Availability is also controlled by transducer and preset via the EPM.

The software applications are supported by all EPIQ and Affiniti models running software version 13.0 or higher.

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.

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler and Harmonic Imaging.

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.

Affiniti Intended Use

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

Affiniti Indications for Use:

The intended use of Affiniti Series Diagnostic Ultrasound Systems 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), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler and Harmonic Imaging.

The clinical environments where the Affiniti diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

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 and Affiniti Ultrasound System Indications for Use due to the introduction of the AutoMeasure software applications

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the change to AutoMeasure V3 software applications to the EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System. The subject device is substantially equivalent to the predicate device (K240850).

The following tables provide an overview of the comparison of similarities and differences between the proposed device and the predicates.

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Table 1: Comparison to Predicate for modification of AutoMeasure V3 onto EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate 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.	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.	Identical to predicate
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.	Identical to predicate
USA FDA Classification	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	Identical to predicate
Primary Regulation Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Identical to predicate

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Feature	EPIQ Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical to predicate
Secondary Product Codes	ITX IYO OBJ QIH	ITX IYO OBJ QIH	Identical to predicate
Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Identical to predicate
Secondary Regulation Number	21 CFR 892.1570 21 CFR 892.1560 21 CFR 870.1200 21 CFR 892.2050	21 CFR 892.1570 21 CFR 892.1560 21 CFR 870.1200 21 CFR 892.2050	Identical to predicate
Reusable-Systems and Transducers	Yes	Yes	Identical to predicate
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical to predicate
Application Description	Auto Measure is an optional software feature on the EPIQ Series Diagnostic Ultrasound System that provides the end user with semiautomated adult echocardiography 2D, Doppler or M-mode measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG. 2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam LA Vol, A2Cs LA Vol, A4Cs LA Diameter a.p. (PLAX) RA Volume	Auto Measure is an optional software feature on the EPIQ Series Diagnostic Ultrasound System that provides the end user with semiautomated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG. 2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A'	Similar to the reference device features. The functionality and workflow of the AutoMeasure V3 software is Identical to predicate where Auto Measure quantifies image data acquired on the Philips EPIQ Ultrasound System through an AI based algorithm that used a trained machine-learning model. Compared to predicate only new measurements and detectors are added to the existing measurements. Clinical performance studies were completed, and the results showed safety and effectiveness

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Feature	EPIQ Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
	AoR Diam(2D) = Ao Annlus diam Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel, MR VTI TR VTI M-Modes include the following: TAPSE	Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	
Semi-Automation Technology	AutoMeasure V3 is created semi-automatically using machine learning algorithm without user interaction. Semi-automated adult echocardiography 2D, Doppler and M-mode measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.	AutoMeasure V3 is created semi-automatically using machine learning algorithm without user interaction. Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.	Subject device uses identical method for contour generation as the reference device K240850. The only difference is the algorithm is new M-mode measurement is added, new detectors are added, and existing detectors are re-trained based on new literature available.
User Interface	User selects an adult echocardiography 2D, Doppler or M-mode measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	Similar. The proposed AutoMeasure V3 software allows very similar semi-automated measurements as the reference software application AutoMeasure. The proposed AutoMeasure V3 software adds additional M-mode measurement and new detectors to the existing measurements (2D and Doppler).

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Table 2: Comparison to Predicate for introduction of AutoMeasure V3 onto Affiniti

Feature	Affiniti Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	Affiniti Series Diagnostic Ultrasound System K240850 Predicate 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.	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 Affiniti 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 Affiniti Series Diagnostic Ultrasound System.	Identical to predicate
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.	Identical to predicate
USA FDA Classification	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	Identical to predicate
Primary Regulation Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Identical to predicate

PHILIPS

Feature	Affiniti Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical to predicate
Secondary Product Codes	ITX IYO OBJ QIH	ITX IYO OBJ QIH	Identical to predicate
Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Identical to predicate
Secondary Regulation Number	21 CFR 892.1570 21 CFR 892.1560 21 CFR 870.1200 21 CFR 892.2050	21 CFR 892.1570 21 CFR 892.1560 21 CFR 870.1200 21 CFR 892.2050	Identical to predicate
Reusable-Systems and Transducers	Yes	Yes	Identical to predicate
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical to predicate
Application Description	Auto Measure is an optional software feature on the Affiniti Series Diagnostic Ultrasound System that provides the end user with semiautomated adult echocardiography 2D, Doppler or M-mode measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG. 2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam LA Vol, A2Cs LA Vol, A4Cs LA Diameter a.p. (PLAX)	Auto Measure is an optional software feature on the Affiniti Series Diagnostic Ultrasound System that provides the end user with semiautomated adult echocardiography 2D or Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG. 2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT	Similar to the reference device features. The functionality and workflow of the AutoMeasure V3 software is Identical to predicate where AutoMeasure quantifies image data acquired on the Philips Affiniti Ultrasound System through an AI based algorithm that used a trained machine-learning model. Compared to predicate only new measurements and detectors are added to the existing measurements. Clinical performance studies were completed, and the results showed safety and effectiveness

PHILIPS

Feature	Affiniti Series Diagnostic Ultrasound System Feature: AutoMeasure V3 Proposed Device	Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
	RA Volume AoR Diam(2D) = Ao Annlus diam Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel, MR VTI TR VTI M-Modes include the following: TAPSE	Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	
Semi-Automation Technology	AutoMeasure V3 is created semi-automatically using machine learning algorithm without user interaction. Semi-automated adult echocardiography 2D, Doppler and M-mode measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.	AutoMeasure V3 is created semi-automatically using machine learning algorithm without user interaction. Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements.	Subject device uses identical method for contour generation as the reference device K240850. The only difference is the algorithm is expansion to new M-mode measurement, new detectors and existing detectors re-trained based on new literature available.
User Interface	User selects an adult echocardiography 2D, Doppler or M-mode measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.	Similar. The proposed AutoMeasure V3 software allows very similar semi-automated measurements as the reference software application AutoMeasure. The proposed AutoMeasure V3 software adds additional M-mode measurement and new detectors to the existing measurements (2D and Doppler).

VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System, including AutoMeasure V3 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 System and Affiniti Series Diagnostic Ultrasound 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 AutoMeasureV3 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 AutoMeasure V3 software applications.

This study evaluated the performance of AutoMeasure V3 software in automation of measurement from cardiac TTE clips across a diverse set of subject demographics, body habitus and parameters' distribution. Adult subjects (18 years of age and above) from whom the study data were sampled were enrolled in hospital settings at multiple institutions, including USA, Asia and Europe. Subjects were enrolled at institutions between 2015 and June 2024, and the timeframes varied for different hospitals. Patients referred for clinical TTE as well as healthy volunteers were invited to participate. Data independence was ensured by adhering to Philips procedure related to consistent data handling and project documentation independent of the data scientist. The study evaluated the performance of the AutoMeasure V3 software, where 7127 transthoracic echocardiography (TTE) cardiac clips from 3964 subjects were used for assessment of AutoMeasure V3 parameters (measurements) and compared to ground truth. The ground truth for the study was defined as Standard of Care (SOC) measurements obtained during initial subject visit, performed by qualified healthcare professional(s).

The subjects whose TTE clips were used in the study were:

	Subjects (mean ± SD (n) (min, max) or % (n/N))
Age (years)	59.00±16.66 (3964);(18.00;100.00)
Gender	
Male	48.56% (1925/3964)
Female	51.44% (2039/3964)
Race	

Asian	2.70% (107/3964)
Black or African American	45.18% (1791/3964)
White	30.25% (1199/3964)
Other/Mixed	21.85% (866/3964)
Unknown	0.03% (1/3964)
BMI (kg/ m^2)	28.85±7.06 (3964);(12.40;63.60)

In addition, the performance of the software was accessed in analysis stratified by demographic variables (age, BMI, gender and race) and clinical status (healthy, suspected of disease).

The results of the 32 hypotheses tested, demonstrated high agreement of AutoMeasure V3 software with Standard of Care Measurements (ground truth) obtained during initial subject exam, by producing confidence intervals for the limits of agreement, for each parameter (hypothesis) tested, meeting the pre-defined acceptance criteria for the study.

Taken together, the results of the study demonstrated clinically reasonable, relevant and meaningful performance of the AutoMeasure V3 software supporting automation of measurements during cardiac TTE exams. Specifically, success on the hypotheses testing for AutoMeasure V3 agreement with ground truth measurements indicate that the safety and effectiveness of the proposed software is acceptable and aligns with previously reported agreement for cardiac assessment. Since the acceptance criteria were based on inter-observer data for echocardiographic measurements, the AutoMeasure V3 performance supports the conclusion that the algorithm behaves like any average human observer. Therefore, the clinical acceptability of AutoMeasure V3 is met. Lastly, the AutoMeasure V3 software is a semi-automated quantitative imaging algorithm, and users are generally expected to review and concur with the initialization and generated results. The users can also edit algorithm generated measurements and outputs based on their clinical expertise.

Since this is a software-only change and no new hardware was added, no acoustic output, cleaning and disinfectants, thermal, electrical, electromagnetic, and mechanical safety testing were required. Biocompatibility testing is not needed for the subject EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound with AutoMeasure V3. The transducer patient contact materials and manufacturing processes are not impacted by the release of the subject EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound with AutoMeasure V3.

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound Systems with AutoMeasure V3 software applications.

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

Results of the testing 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.