May 21, 2025

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

Re: K243793
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, QIH, OBJ
Dated: December 10, 2024
Received: May 8, 2025

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,

Lora D. Weidner, Ph.D.
Assistant Director
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)*

K243793

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHILIPS

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

510(k) Number: K243793

Date Prepared: December 10, 2024

Date Modified: May 21, 2025

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431 USA

Contact Information

Deval Patel
Principal Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, WA 98021-8431 USA
+1 (949) 502-1823

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
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*

*EPIQ only

Device Class

Class II

Review Panel

Radiology

Predicate Device

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

III. Device Description

The R-Trigger algorithm software feature on Philips EPIQ and Affiniti Ultrasound System is intended to support detection of R-wave peak (R-trigger) as an input to certain TTE clinical applications, initially including AutoStrain LV, AutoEF, 2D Auto LV (collectively referred to as "AutoStrain"), and AutoMeasure applications. The R-trigger algorithm is planned to be implemented as workflow enhancement for transthoracic clinical applications on EPIQ and Affiniti Ultrasound Systems in the VM13 software release.

The Auto-Measure and AutoStrain features, cleared on Philips EPIQ and Affiniti systems (K211597, K190913 resp.) support users during B-mode (2D), CW-, PW- and TDI-Doppler measurements by automating some of the measurements needed to complete a routine transthoracic echo (TTE) exam for adult patients.

The current AutoMeasure and AutoStrain applications require input from physio signal (ECG) using electrodes, because the modules and their detectors work on single cardiac cycles, starting and ending with the End Diastole (ED) or more precisely with delimiting R-trigger events as a good approximation. Determining the R-triggers is currently done on the EPIQ and Affiniti Ultrasound Systems by a dedicated physio board. However, in some cases, the physio signal is not available, either because it was never obtained or because the data were not saved. To enable clinical users to be able to use AutoMeasure and AutoStrain application without the R-trigger (ECG based) input, R-trigger feature (non-ECG-based) has been developed.

There are no hardware changes to the EPIQ and Affiniti systems due to change to the introduction of the R-Trigger software application.

The software application is 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.

PHILIPS

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 R-Trigger software application.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the R-Trigger software application 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.

PHILIPS

Table 1: Comparison to Predicate for introduction of **R-Trigger** onto EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Feature: R-Trigger 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
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical to predicate

PHILIPS

Feature	EPIQ Series Diagnostic Ultrasound System Feature: R-Trigger Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
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
Device Track	Track 3	Track 3	Identical to predicate
Application Description	The R-Trigger AI software feature on Philips EPIQ and Affiniti Ultrasound System is intended to support detection of R-wave peak (R-trigger) as an input to AutoStrain and AutoMeasure applications, as well as other cardiac clinical applications. The R-trigger algorithm is planned to be implemented as workflow enhancement to the AutoStrain (previously cleared by FDA; K190913) and AutoMeasure (previously cleared by FDA; K211597) applications on EPIQ and Affiniti Ultrasound Systems in the VM13 software release.	The EPIQ ultrasound systems currently detects R-Trigger events by processing a patient's ECG signal using the on-cart physio board.	Similar. In the subject device, the R-Trigger algorithm will provide an additional method of determining R-Trigger events for a patient's acquired ultrasound clip. Currently, the Ultrasound System requires an ECG signal, which is processed by the on-cart physio board, to detect R-Trigger events in the cardiac cycle. These detected events are used as input into various cardiac clinical applications. In the subject device, the R-Trigger algorithm will serve as a back-up for R-Trigger event detection. Detecting events from the ECG signal on the system will still be the preferred method. In case the ECG signal is not usable or not available, the new R-Trigger algorithm will detect the events. From a user perspective, their only difference is that they will be able to use certain cardiac clinical applications on acquired clips which do not have a usable ECG signal in the subject device. Otherwise, there are not able changes visible to the user as both methods work in the background.

PHILIPS

Table 2: Comparison to Predicate for introduction of **R-Trigger** onto Affiniti

Feature	**Affiniti Series Diagnostic Ultrasound System Feature: R-Trigger 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), Musculoskeletal (Conventional), Musculoskeletal (Superficial), 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), Musculoskeletal (Conventional), Musculoskeletal (Superficial), 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
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical to predicate

PHILIPS

Feature	Affiniti Series Diagnostic Ultrasound System Feature: R-Trigger Proposed Device	Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
Secondary Product Codes	ITX IYO QIH	ITX IYO QIH	Identical to predicate
Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Automated Radiological Image Processing Software	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Automated Radiological Image Processing Software	Identical to predicate
Secondary Regulation Number	21 CFR 892.1570 21 CFR 892.1560 21 CFR 892.2050	21 CFR 892.1570 21 CFR 892.1560 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
Device Track	Track 3	Track 3	Identical to predicate
Application Description	The R-Trigger AI software feature on Philips EPIQ and Affiniti Ultrasound System is intended to support detection of R-wave peak (R-trigger) as an input to AutoStrain and AutoMeasure applications, as well as other cardiac clinical applications. The R-trigger algorithm is planned to be implemented as workflow enhancement to the AutoStrain (previously cleared by FDA; K190913) and AutoMeasure (previously cleared by FDA; K211597) applications on EPIQ and Affiniti Ultrasound Systems in the VM13 software release.	The Affiniti ultrasound systems currently detects R-Trigger events by processing a patient's ECG signal using the on-cart physio board.	Similar. In the subject device, the R-Trigger algorithm will provide an additional method of determining R-Trigger events for a patient's acquired ultrasound clip. Currently, the Ultrasound System requires an ECG signal, which is processed by the on-cart physio board, to detect R-Trigger events in the cardiac cycle. These detected events are used as input into various cardiac clinical applications. In the subject device, the R-Trigger algorithm will serve as a back-up for R-Trigger event detection. Detecting events from the ECG signal on the system will still be the preferred method. In case the ECG signal is not usable or not available, the new R-Trigger algorithm will detect the events. From a user perspective, their only difference is that they will be able to use certain cardiac clinical applications on acquired clips which do not have a usable ECG signal in the subject device. Otherwise, there are not able changes visible to the user as both methods work in the background.

VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System, including R-Trigger software application, 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 R-Trigger software application. 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 R-Trigger software application.

A retrospective data analysis study was executed to evaluate the performance of R-trigger AI based software in detection of R-wave time stamp and subsequent input of the time stamp into AutoMeasure and AutoStrain applications' clinical outputs. The study was executed on cardiac TTE clips acquired with Philips Ultrasound systems from a diverse set of subject demographics, body habitus and parameters' distribution. There were 3 primary endpoints in the study. Primary endpoint #1 evaluated the performance of the R-Trigger (non-ECG) algorithm in isolation, primary endpoints #2 and #3 evaluated the clinical impact of the R-Trigger algorithm outputs, which were used as an input to the AutoMeasure and AutoStrain clinical application, respectively. Total of 35 hypotheses covering 3 endpoints were tested in this study in a pre-defined hierarchical order with pre-defined acceptance criteria. A total of 7309 cardiac clips from 3964 were used for analysis of R-trigger AI-based algorithm covering the 3 endpoints. The demographic for the subjects associated with the clips included in the study are presented in the tables below and additionally refer to Table 6 and Table 7 for detail different market regions stratified by demographics and age and BMI stratification by modes:

Table 1: AutoMeasure Subjects' Demographics

	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/ m2)	28.85±7.06 (3964);(12.40;63.60)

Table 2: AutoStrain Subjects' Demographics

	Subjects (mean ± SD (n) (min, max) or % (n/N))
Age (years)	48.87±18.60 (82) (20.00, 86.00)
Gender	
Male	45.12% (37/82)
Female	54.88% (45/82)
Race	
Asian	24.39% (20/82)
Black or African American	7.32% (6/82)
White	36.59% (30/82)
Other/Mixed	31.71% (26/82)
BMI (kg/ m2)	24.37±3.47 (82) (16.40, 33.80)

Table 3: R-trigger Time Stamp Subjects' Demographics

	Subjects (mean ± SD (n) (min, max) or % (n/N))
Age (years)	58.51±17.00 (1894); (18.00;100.00)
Gender	
Male	47.31% (896/1894)
Female	52.69% (998/1894)
Race	
Asian	3.27% (62/1894)
Black or African American	42.77% (810/1894)
White	31.36% (594/1894)
Other/Mixed	22.60% (428/1894)
BMI (kg/ m2)	28.51±6.81(1894); (12.40;69.50)

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 35 hypotheses demonstrated high agreement of R-trigger AI based algorithm in both technical and clinical assessments when compared to ECG-based R-trigger. The mean differences, inclusive of 95% confidence intervals, reported in the study for all endpoints fall within the clinical

ranges, as such the clinical acceptability for the bias (mean difference) is also met.

The study results produced confidence intervals for the limits of agreement and correlation, for each parameter (hypothesis) tested, meeting the pre-defined acceptance criteria for the study. The results for all three primary endpoints are shown below:

Table 4: Relative Bland-Altman Analysis for R-trigger AI-based workflow vs Ground Truth

Endpoint	Order of Hypothesis Testing	Outcomes Comparison	Lower LoA (95% CI)	Upper LoA (95% CI)	Measurement Type	Acceptance Criteria
Endpoint 1: R-trigger	1	R-wave peak time stamp	-58.06ms (**-59.34**, -56.78)	69.69ms (68.41, **70.97**)	Time Stamp	[-99.5ms, 99.5ms]
Endpoint 3: AutoStrain*	N/A	EF	-6.64% (**-7.60**%, -5.68%)	6.52% (5.56%, **7.49**%)	EF	[20%, 20%]
	N/A	GLS	-5.25% (**-5.72**%, -4.79%)	4.63% (4.16%, **5.10**%)	GLS	[7%, 7%]
Endpoint 2: AutoMeasure	4	MV E Vel	-12.00 % (**-13.17%**, -10.84 %)	12.98 % (11.81 %, **14.14%**)	Pw/cw Doppler velocity	[-25%, 25%]
	5	LVIDd	-9.33 % (**-9.84%,** -8.81 %)	9.33 % (8.82 %, **9.85%**)	Distance	[-30%, 30%]
	6	RVLd	-8.60 % (**-9.57 %,** -7.62 %)	5.35 % (4.38 %, **6.33%**)	Distance	[-30%, 30%]
	7	TR VTI	-12.26 % (**-15.15 %,** -9.37 %)	17.44 % (14.54 %, **20.33%)**	Pw/cw Doppler VTI	[-29%, 29%]
	8	PV VTI	-13.73 % (**-15.87 %,** -11.59 %)	17.91 % (15.78 %, **20.05%**)	Pw/cw Doppler VTI	[-29%, 29%]
	9	LA Diameter a.p. (PLAX)	-8.05 % (**-9.41 %,** -6.70 %)	9.39 % (8.03 %, **10.74%**)	Distance	[-30%, 30%]
	10	MV A Vel	-15.95 % (**-17.44 %,** -14.47 %)	14.69 % (13.20 %, **16.17%**)	Pw/cw Doppler velocity	[-25%, 25%]
	11	Ao SV diam	-7.60 % (**-8.42 %,** -6.77 %)	9.30 % (8.47 %, **10.12%**)	Distance	[-30%, 30%]
	12	LVOT diam	-9.84 % (**-10.51 %,** -9.16 %)	9.55 % (8.87 %, **10.22%**)	Distance	[-30%, 30%]
	13	LVOT VTI	-10.97 % (**-12.66 %,** -9.28 %)	14.41 % (12.72 %, **16.09%**)	Pw/cw Doppler VTI	[-29%, 29%]
	14	AoR Diam(2D) = Ao Annlus diam	-13.02 % (**-14.60 %,** -11.44 %)	13.00 % (11.42 %, **14.58%**)	Distance	[-30%, 30%]
	15	RV S'(I)	-16.11 % (**-17.59 %,** -14.63 %)	17.97 % (16.49 %, **19.45%**)	TDI velocity	[-28%, 28%]

PHILIPS

Endpoint	Order of Hypothesis Testing	Outcomes Comparison	Lower LoA (95% CI)	Upper LoA (95% CI)	Measurement Type	Acceptance Criteria
	16	LV A'(s)	-15.85 % (**-18.53 %,** -13.17 %)	17.53 % (14.85 %, **20.22%**)	TDI velocity	[-28%, 28%]
	17	TR Vmax	-9.66 % (**-11.95 %,** -7.38 %)	13.83 % (11.54 %, **16.12%**)	Pw/cw Doppler velocity	[-25%, 25%]
	18	AV VTI	-12.85 % (**-14.06 %,** -11.64 %)	14.77 % (13.56 %, **15.98%**)	Pw/cw Doppler VTI	[-29%, 29%]
	19	Ao Asc diam	-9.63 % (**-10.49 %,** -8.76 %)	10.64 % (9.77 %, **11.50%**)	Distance	[-30%, 30%]
	20	TAPSE	-19.65 % (**-22.85 %,** -16.44 %)	18.23 % (15.02 %, **21.43%**)	Distance (TAPSE/MAPSE)	[-34%, 34%]
	21	Ao STJ diam	-7.61 % (**-8.26 %,** -6.95 %)	8.83 % (8.17 %, **9.49%**)	Distance	[-30%, 30%]
	22	RA Volume (A4Cs)	-27.08 % (**-29.52 %,** -24.63 %)	32.89 % (30.45 %, **35.33%**)	Volume Contour	[-46%, 46%]
	23	LA Vol (A2Cs)	-21.72 % (**-23.61 %,** -19.82 %)	20.47 % (18.58 %, **22.37%**)	Volume Contour	[-46%, 46%]
	24	LA Vol (A4Cs)	-23.80 % (**-25.88 %,** -21.73 %)	21.51 % (19.44 %, **23.58%**)	Volume Contour	[-46%, 46%]
	25	LV A'(l)	-17.60 % (**-20.15 %,** -15.06 %)	21.44 % (18.90 %, **23.98%**)	TDI velocity	[-28%, 28%]
	26	LV E'(s)	-19.45 % (**-21.25 %,** -17.65 %)	20.89 % (19.08 %, **22.69%**)	TDI velocity	[-28%, 28%]
	27	LV E'(l)	-19.21 % (**-21.04 %,** -17.37 %)	21.62 % (19.78 %, **23.45%**)	TDI velocity	[-28%, 28%]
	28	LVPWd	-14.13 % (**-14.89 %,** -13.36 %)	13.59 % (12.82 %, **14.35%**)	Distance Short	[-40%, 40%]
	29	MV Dec. Time	-24.95 % (**-26.87 %,** -23.03 %)	23.62 % (21.70 %, **25.54%**)	Doppler Time Interval	[-35%, 35%]
	30	IVSd	-15.82 % (**-16.65 %,** -15.00 %)	14.21 % (13.38 %, **15.04%**)	Distance Short	[-40%, 40%]
	31	TV Ann diam ant-post	-14.91 % (**-17.46 %,** -12.37 %)	14.74 % (12.20 %, **17.29%**)	Distance	[-30%, 30%]
	32	LVIDs	-13.31 % (**-14.27 %,** -12.34 %)	12.98 % (12.02 %, **13.95%**)	Distance	[-30%, 30%]
	33	RVDd base (RVD1)	-12.60 % (**-13.27 %,** -11.92 %)	12.68 % (12.00 %, **13.36%**)	Distance	[-30%, 30%]

Endpoint	Order of Hypothesis Testing	Outcomes Comparison	Lower LoA (95% CI)	Upper LoA (95% CI)	Measurement Type	Acceptance Criteria
	34	RVDd mid (RVD2)	-20.45 % (**-21.80 %,** -19.11 %)	16.86 % (15.51 %, **18.21%**)	Distance	[-30%, 30%]
	35	MR VTI	-14.36 % (**-15.90 %,** -12.82 %)	17.04 % (15.50 %, **18.58%**)	Pw/cw Doppler VTI	[-29%, 29%]

*EF/GLS were assessed via Pearson's Correlation for pre-specified hypothesis testing order. See table 5.

Table 5: Pearson's Correlation for R-trigger AI-based workflow vs ground Truth

Order of Hypothesis Testing	Outcomes Comparison	Pearson's correlation coefficient (r) (95% CI)	Acceptance Criteria
2	EF	0.892 (**0.853**,0.922)	LCB >0.8
3	GLS	0.992 (**0.990**,0.994)	LCB >0.8

Table 6: The performance analysis of the detectors in different market regions stratified by demographics

	B-mode apical			B-mode PLAX			cw Doppler			pw Doppler			TDI			M-Mode		
	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]	Bias [ms]	Lower 95% LoA (with 97.5 CI) [ms]	Upper LoA (with 97.5% CI) [ms]
Ethnicity "black"	17.7	-60.6	96.1	12.5	-60.3	85.3	-2.7	-64.9	59.6	-4.8	-80.3	70.6	5.2	-70.9	81.3	-1.2	-73.7	71.3
Ehnicity "other"	20.5	-53.0	94.1	20.6	-52.1	93.3	-2.5	-67.0	62.0	-4.0	-56.0	55.3	5.0	-72.0	82.0	-7.5	-67.8	52.9
Ethnicity "white"	17.3	-53.7	88.2	21.5	-45.4	88.3	-5.2	-72.3	61.8	-0.4	-69.8	68.9	10.8	-48.6	70.2	-2.5	-91.1	86.1
Cardially healthy	21.9	-35.9	79.7	24.9	-33.6	83.5	-3.6	-46.1	32.8	-0.6	-39.4	38.3	2.6	-66.5	71.7	-8.2	-66.0	49.7
Patients with echo indication	16.7	-62.0	95.4	15.6	-55.7	86.9	-3.5	-69.4	62.4	-2.6	-76.3	71.1	8.1	-63.0	79.3	-2.4	-83.1	78.3
Region North America (USA1, USA2, Canada, Mexico)	17.0	-56.7	90.6	16.3	-52.9	85.5	-3.6	-67.6	60.5	-2.6	-72.5	67.2	7.4	-64.6	79.5	-3.7	-77.3	69.9
Region Rest of world	26.2	-38.2	90.5	28.0	-35.1	91.2	-2.8	-53.0	47.4	1.2	-35.4	37.8	3.4	-57.5	64.4	-3.8[1]	-68.7[1]	61.0[1]

[1] Due to sample size issues, global performance is reported instead of rest of world data

PHILIPS

Table 7: Performance results of the different age – and BMI groups.

Age [years]	2D ALAX mean [ms]	2D ALAX std [ms]	2D ALAX N	2D PLAX mean [ms]	2D PLAX std [ms]	2D PLAX N	CWD mean [ms]	CWD std [ms]	CWD N	PWD mean [ms]	PWD std [ms]	PWD N	TDI mean [ms]	TDI std [ms]	TDI N	Mmode mean [ms]	Mmode std [ms]	Mmode N
< 30	22,3608	29,7713	464	20,4984	29,4916	276	-3,2113	21,604	770	-5,9128	22,2969	522	2,4613	22,485	708	0,1614	23,7552	60
[30, 40)	15,5169	27,0963	590	21,4149	33,2061	452	-6,3028	26,6602	1116	0,1642	23,4811	888	1,1274	26,0283	912	-8,6466	24,2302	62
[40, 50)	18,7653	42,5653	534	12,1518	29,6201	442	-4,4	28,6318	1656	-4,0744	21,9616	1046	5,3757	32,6808	992	-6,1834	13,7949	82
[50, 60)	14,7195	34,6072	816	14,7519	28,2333	522	-3,2839	37,7419	1770	-0,8162	31,5805	1188	5,6068	36,7938	1240	-8,4599	25,889	118
[60, 70)	19,0654	32,6803	946	21,1265	32,6609	786	-3,0363	29,7499	2346	-3,9253	42,291	1110	4,6591	38,8012	1546	8,0672	40,9966	118
[70, 80)	20,1622	33,3848	962	18,4896	33,6052	520	-4,6104	32,7933	2030	-3,5902	33,4302	1252	11,6894	32,1315	1534	-10,0727	35,7687	138
>= 80	18,0821	50,1052	266	9,7551	41,2727	248	3,206	28,1476	760	12,4942	42,5802	306	21,6097	40,9872	472	10,9446	21,0323	18
Total			4578			3246			10448			6312			7404			596

BMI [kg/m²]	2D ALAX mean [ms]	2D ALAX std [ms]	2D ALAX N	2D PLAX mean [ms]	2D PLAX std [ms]	2D PLAX N	CWD mean [ms]	CWD std [ms]	CWD N	PWD mean [ms]	PWD std [ms]	PWD N	TDI mean [ms]	TDI std [ms]	TDI N	Mmode mean [ms]	Mmode std [ms]	Mmode N
< 18.5	19,5505	28,3718	210	18,7511	29,4978	148	-6,0925	25,9067	430	-0,3086	23,7911	194	-3,2873	27,7559	192	-49,2954	28,5332	12
[18.5, 25.0)	18,0509	35,7453	1608	19,8614	36,0952	1038	-4,0071	29,1289	3714	-3,3768	28,6633	2404	4,6081	36,3333	2778	-8,5554	38,4066	230
[25.0, 30.0)	20,3118	32,0369	1410	18,4808	32,469	930	-2,3525	27,6045	2718	0,4405	31,5529	1714	9,7347	32,522	2196	2,7052	26,8123	170
[30.0, 35.0)	15,5626	34,5971	744	15,4517	32,3496	592	-0,9768	31,9309	1900	-1,3386	24,6602	1004	8,0421	34,47	1170	-5,0901	23,6583	60
[35.0, 40.0)	15,7476	38,8853	442	14,4673	25,3248	374	-4,5722	36,7892	1148	-5,1252	35,0944	624	7,2621	31,0496	742	-5,0401	12,8211	80
>= 40.0	21,3035	44,2133	164	11,6543	25,0333	164	-10,5029	40,7001	538	-3,3229	58,5367	372	6,2726	31,0726	326	12,1638	16,8775	44
Total			4578			3246			10448			6312			7404			596

Total of 35 hypotheses covering 3 endpoints were tested in this study in a pre-defined order with pre-defined acceptance criteria. Study produced confidence intervals for the limits of agreement and correlation, for each parameter (hypothesis) tested, meeting the pre-defined acceptance criteria for the study. Lastly, both AutoMeasure and AutoStrain applications are semi-automated quantitative imaging tools and users are generally expected to review and concur with the initialization and generated results. The users can also edit the application(s) 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 R-Trigger. 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 R-Trigger.

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 R-Trigger software application.

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.