May 9, 2025

Philips Ultrasound LLC
Vera Kong
Regulatory Affairs Manager
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K251110
Trade/Device Name: EPIQ Series Diagnostic Ultrasound Systems; Affiniti Series Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH, OBJ
Dated: April 11, 2025
Received: April 11, 2025

Dear Vera Kong:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YANNA S. KANG -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251110

Please provide the device trade name(s).

EPIQ Series Diagnostic Ultrasound Systems;
Affiniti Series Diagnostic Ultrasound Systems

Please provide your Indications for Use below.

EPIQ:
The intended use of Philips EPIQ 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), 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 Philips EPIQ 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 judgment and best clinical procedure.

Affiniti:
The intended use of the 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 judgment and best clinical procedure.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Special 510(k) Summary

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

510(k) Number: K251110

Date Prepared: Apr 11, 2025

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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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
Automated Radiological Image Processing Software	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
K240850; Philips Affiniti Series Diagnostic Ultrasound System

Reference Devices

K243862; LVivo Software Application
K243235; LVivo Software Application

III. Device Description

The purpose of this Special 510(k) Pre-Market Notification is to modify the Segmental Wall Motion and introduce Auto EF with contrast software application onto the Philips EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound Systems. SWM algorithm was previously cleared (K243862) and Auto EF contrast algorithm(K243235) was also previously cleared. The current software release version VM 13, replaces the previous version of the segmental wall motion algorithm included in version 11 of the software release with the current cleared version (K243862) without any modifications, and integrates Auto EF contrast algorithm(K243235) without any modifications into one software release.

The SWM v2 software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. For input, the SWM algorithm uses 3 apical views (A4C, A2C and A3C) and performs border detection and tracking to identify each of the LV segments based on the three views. The SWM v2 software is a semi-automated quantitative imaging algorithm, as users are generally expected to review and concur with the initial and generated results. The users can also manually edit algorithm-generated segmental wall motion scores for individual segments based on their clinical expertise.

Auto EF with contrast is an AI based automated software feature that assists clinicians with assessing Left Ventricular Ejection Fraction (LVEF) from images acquired with contrast agent as part of an adult transthoracic echo (TTE) examination. The feature is located within the Philips Auto EF Adv application. Auto EF with contrast uses 2 apical views (Apical four chamber view (A4C), Apical two chamber (A2C)) and provides EF for each view and a biplane Simpsons EF.

No hardware changes to the EPIQ or Affiniti systems were made due to the SWM v2 and Auto EF with contrast, and existing, cleared Philips TTE transducers are used with these software applications.

The SWM v2 and Auto EF with contrast feature is supported by all EPIQ models running software version 13.0 or higher including EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, EPIQ 5, as well as all Affiniti models including Affiniti CVx, Affiniti 70, Affiniti 50, and Affiniti 30. The SWM v2 and Auto EF with contrast software features are associated with the cardiac adult indication.

IV. Intended Use and Indications for Use

EPIQ Intended Use:

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

EPIQ Indications for Use:

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

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

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

Note: There are no changes to the EPIQ Ultrasound System Indications for Use due to modifythe Segmental Wall Motion and the introduction of Auto EF with contrast software applications. The software applications are associated with the Cardiac Adult indication.

Affiniti Intended Use:

The intended use of Affiniti Series Diagnostic Ultrasound Systems 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, 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 Affiniti Ultrasound System Indications for Use due to modify Segmental Wall Motion and the introduction of Auto EF with contrast software applications. The software applications are associated with the Cardiac Adult indication.

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V. Comparison of Technological Characteristics with the Predicate

The purpose of this Special 510(k) Pre-Market Notification is to modify Segmental Wall Motion and introduce Auto EF with contrast software application onto the Philips EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound Systems. Table 1 shows an evaluation of the subject device to the predicate device (K240850) to allow for comparison of the product intended use, Indications for Use, technological characteristics and other aspects of use and design.

Table 1 Comparison to Predicate -EPIQ and Affiniti

Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Feature: *SWM Version 2 and Auto EF with contrast* Proposed Device	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	LVivo Software Application K243862 Feature (SWM v2) Reference Predicate Device	LVivo Software Application K243235 Feature (Auto EF with contrast) Reference 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.	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease and Age>18. In addition, it has the ability to provide Quality Score feedback.	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease. In addition, it has the ability to provide Quality Score feedback. (For Adults Age>18)	Identical to predicate
Intended Users	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	Trained healthcare professionals	Trained healthcare professionals	Identical to predicate

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Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Feature: *SWM Version 2 and Auto EF with contrast* Proposed Device	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	LVivo Software Application K243862 Feature (SWM v2) Reference Predicate Device	LVivo Software Application K243235 Feature (Auto EF with contrast) Reference Predicate Device	Comparison
Intended User Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Professional healthcare environments	Professional healthcare environments	Identical to predicate
USA FDA Classification	Class II	Class II	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	QIH	QIH	Identical to predicate
Primary Regulation Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Medical image management and processing system.	Automated Radiological Image Processing Software	Identical to predicate
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.2050	21 CFR 892.2050	Identical to predicate
Secondary Product Codes	ITX IYO OBJ QIH	ITX IYO OBJ QIH	N/A	N/A	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	N/A	N/A	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	N/A	N/A	Identical to predicate
Reusable-Systems and Transducers	Yes	Yes	No, software-only	No, software-only	Identical to predicate
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	No, software-only	No, software-only	Identical to predicate

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Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Feature: *SWM Version 2 and Auto EF with contrast* Proposed Device	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System K240850 Predicate Device	LVivo Software Application K243862 Feature (SWM v2) Reference Predicate Device	LVivo Software Application K243235 Feature (Auto EF with contrast) Reference Predicate Device	Comparison
Application Description	The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations.	The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations.	The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations.	SWM: Not applicable – the focus of this application was on the addition of the Contrast EF software feature.	Identical to reference predicate Note :Contrast EF means Auto EF with contrast
	Auto EF with contrast is an AI based automated software feature that assists clinicians with assessing Left Ventricular (LV) Ejection Fraction (EF) from images acquired with contrast agent as part of an adult transthoracic echo (TTE) examination. The feature is located within the Philips Auto EF Adv application. Auto EF with contrast uses 2 apical views (Apical four chamber view (A4C), Apical two chamber (A2C)) and provides EF for each view and a biplane Simpsons EF.	Auto EF is a semi-automated (non AI) software feature that assists clinicians with assessing Left Ventricular (LV) Ejection Fraction (EF) from images acquired as part of an adult transthoracic echo (TTE) examination application. . supports The Auto EF feature supports standard Echo images.	Auto EF with contrast: Not applicable – the focus of this application was on the revision in SWM algorithm	LVivo CE-EF is an AI based automated software feature that assists clinicians with assessing Left Ventricular (LV) Ejection Fraction (EF) from images acquired with contrast agent as part of an adult transthoracic echo (TTE) examination. LVivo CE-EF uses 2 apical views (Apical four chamber view (A4C), Apical two chamber (A2C)) and provides EF evaluation for each view and a biplane Simpsons EF. **Note:** CE means Contrast echocardiography	Identical to reference predicate
SWM scoring adjustment (SWM v2)	Users manually edit wall motion scores using a drop-down selection. Additional interface to set wall motion scores of all segments to Normal	Users manually edit wall motion scores using a drop-down selection	No.	Not applicable	Identical to reference predicate
Segmental wall motion evaluation (SWM v2)_	Yes. Based on the same machine learning algorithm, multiple processing steps were added and the calculated features revised	Yes. Based on the machine learning algorithm	Yes. Based on the same machine learning algorithm, multiple processing steps were added and the calculated features revised	Not applicable	Identical to reference predicate
Border editing (Auto EF with Contrast)	Manual border edit on ED or ES Frame and results recalculation	Manual border edit on ED or ES Frame and results recalculation	Not applicable	Manual border edit on ED or ES Frame and results recalculation	Identical to predicate
EF Evaluation (Auto EF with Contrast)	AI Based EF evaluation for the A4C, A2C and Biplane (Contrast Exams) as part of Auto EF adv	Non-AI based EF evaluation for the A4C, A2C and Biplane (Non Contrast exams) as part of Auto EF	Not applicable	AI based EF evaluation for the A4C, A2C and Biplane	Identical to reference predicate

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, including SWM v2 and Auto EF with contrast 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

Philips Ultrasound tested the subject devices per the following standards to ensure the continued safe and effective performance, given the modifications made to the EPIQ and Affiniti Series Diagnostic Ultrasound Systems:

- IEC 62304 Medical device software – Software life cycle processes, 2006 + A 2015
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices Edition 1.1 2020-06 CONSOLIDATED VERSION
- 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 modification of the subject SWM v2 and the introduction of Auto EF with contrast 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

Since this is a software-only change and no new hardware was added, no acoustic output, cleaning and disinfectant, thermal, electrical, electromagnetic, and mechanical safety testing were required. Biocompatibility testing is not needed for the subject EPIQ and Affiniti Series Diagnostic Ultrasound Systems with SWM v2 and Auto EF with contrast. The transducer patient contact materials and manufacturing processes are not impacted by the release of the subject EPIQ and Affiniti Series Diagnostic Ultrasound Systems with SWM v2 and Auto EF with contrast.

SWM v2

A retrospective data analysis study was conducted to assess the use of Segmental Wall Motion (SWM) v2, 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 SWM v2 application was operated automatically on manually selected clips by an experienced sonographer from the apical views. The automated results were compared to reference results provided using visual estimation by 3 expert cardiologists to ensure that similar trends in performance are seen in terms of sensitivity and specificity (K243862). The acceptance criteria were defined to be specificity and sensitivity of WMSI > 0.675 (Lower Bound of the Confidence Interval) based on predefined prevalence of abnormal cases of 65%, for the primary endpoint, for the study overall. The expected value of the correlation coefficient is 0.8, and lower bound is 0.675, computed for Sensitivity, using a test for one-sample sensitivity with a power of 80%, a one-sided alpha of 0.025, a prevalence of 65%, and a target sensitivity of 0.80. There was no acceptance criteria defined for Philips data only, however the objective was to ensure that similar trends in performance are seen in terms of sensitivity and specificity (K243862).

Two approaches for sensitivity and specificity analyses were tested. The first one compared the average of WMSI provided by ground truthers to the WMSI reported by the SWM v2 software. The second approach utilized the majority agreement between ground truthers. Specifically, a minimum of 2/3 ground truthers were required to provide WMSI =1, for WMSI to be considered normal for the exam, or WMSI>1 to be considered abnormal for the exam. The 2/3 WMSI scores were then

compared to the software WMSI.

WMSI assessment by visual estimation is subject to variability as previously reported (K243862). The results showed opposite but anticipated trends in sensitivity and specificity based on the ground truth definition, due to the inherent variability in visual estimation of WMSI. Importantly, regardless of the methodology used for the ground truth definition, the SWM v2 software applied to Philips data shows performance that aligns with previously reported assessment of the algorithm (K243862). Taken together, the reported sensitivity and specificity of the SWM v2 software as compared to visual estimation of WMSI, indicate that the safety and effectiveness of the proposed subject software, SWM v2, is acceptable and aligns with the previously reported performance.

Auto EF with Contrast

A retrospective data analysis study was conducted to assess the use of Contrast EF, an artificial intelligence (AI) based feature in quantification of Ejection Fraction (EF) in transthoracic (TTE) contrast enhanced clips obtained from subjects referred for clinical TTE exam. The ground truth for the study was obtained following a manual selection of contrast-enhanced A4C and A2C clips (performed by a qualified sonographer) for subsequent manual EF assessment using the Simpson's method of disks (performed by 3 qualified sonographers). The sonographers performed "shoulder to shoulder" consensus meetings and reviewed together the manual measurements. The sonographers then jointly selected the best traced images ("Best Trace") and the resulting LV EF measurements for each one of the clips (A4C and A2C) for each exam. If needed the sonographers manually adjusted the trace, and the EF measurement results were recalculated. A Cardiologist specializing in echo subsequently reviewed the selected A4C and A2C clips with "Best Trace" and the resulting LV EF measurements for each examination. Manual adjustments were performed if needed by the cardiologist. These final measurements of EF for each exam/subject were used as the ground truth in the study. The same A2C and A4C clips were processed automatically through the Contrast EF application to an EF output. The ground truth EF measurements were compared to the Contrast EF automated results for EF (biplane). The acceptance criteria for the study were defined as Lower Confidence Bound for the Pearson's correlation to be >0.75. The expected value of the correlation coefficient is 0.85, and lower bound is 0.75 computed with the criteria of achieving 80% power to detect a difference of -0.10 between the null hypothesis correlation of 0.75 and the alternative hypothesis correlation of 0.85 using a one-sided hypothesis test with a significance level of 0.025. The acceptance criteria were defined in accordance with published literature and previous FDA clearance(s) (K232145).

A sub-analysis was performed on data acquired with Philips systems in support of the Contrast EF algorithm integrated into the EPIQ and Affiniti Systems.

The acceptance criteria for the primary endpoint were met, specifically, the Pearson's correlation coefficient and associated confidence intervals are 0.952 (95%CI 0.919, 0.972).

In addition, the results presented above for correlation and Bland-Altman agreement demonstrate acceptable performance compared to the results previously reported for automated EF analysis utilizing standard echo examinations (K210053) and published literature for automated solutions for EF analysis based on contrast echo. Overall, the data obtained and results from the supporting additional analyses indicates the continued safety and effectiveness of the proposed subject software, Auto EF with contrast, and aligned with the previously reported performance(K243235).

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems with SWM v2 and Auto EF with contrast software applications, with substantial equivalence being demonstrated based on the following attributes:

- Indications for use
- Risk assessment
- Application of design controls
- Established methodologies used to evaluate the changes

- Non-clinical performance testing
- Safety and effectiveness comparisons

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject device continues to meet its intended use, and the modifications made do no raise new or different questions of safety and effectiveness in support of a substantially equivalence determination.