June 18, 2025

Philips Ultrasound LLC
Deval Patel
Principal Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL, WA 98021

Re: K250886
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: May 21, 2025
Received: May 23, 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,

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.

510(k) Number *(if known)*
K250886

Device Name
EPIQ Series Diagnostic Ultrasound Systems;
Affiniti Series Diagnostic Ultrasound Systems

Indications for Use *(Describe)*
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, Intra-cardiac Echo, Intra-luminal, Intraoperative (Vascular), Intraoperative (Cardiac), 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 judgement 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.

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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Special 510(k) Summary

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

510(k) Number: K250886

Date Prepared: June 18, 2025

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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WA 98021-8431 USA

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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

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
Automated Radiological Image Processing Software	892.2050	QIH
Diagnostic Intravascular Catheter	870.1200	OBJ*

*EPIQ only

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III. Device Description

The purpose of this Special 510(k) Pre-Market Notification is to expand the Smart View Select (SVS) software application onto the Affiniti Series Diagnostic Ultrasound Systems and to modify the Smart View Select software application onto both the EPIQ Series Diagnostic Ultrasound Systems.

Smart View Select is an automated software feature that assists the user in selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic (TTE) examination. This feature automatically classifies each acquired image by view and selects an appropriate set of images for left ventricle (LV) analysis. The classification is based on a Deep Learning AI interface engine; the selection is a non-AI algorithm that considers the view classification and image depth to select the optimal set of images.

No hardware changes to the EPIQ or Affiniti systems are required when using SVS, and existing, cleared Philips TTE transducers are used with these software applications.

The SVS v2 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. The SVS v2 feature is supported by the Affiniti models running software version VM13.0 or higher, including Affiniti CVx, Affiniti 70, Affiniti 50, and Affiniti 30. The SVS and SWM 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, and Coded Pulse.

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.

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Note: There are no changes to the EPIQ Ultrasound System Indications for Use due to the modification of the SVS v2 software applications. This 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, and Coded Pulse.

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 the modification of the SVS v2 software application. This software application is associated with the Cardiac Adult indication.

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V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to expand the SVSv2 software application feature to the Affiniti Series Diagnostic Ultrasound System and modify SVS v2 software application to EPIQ. The subject device is substantially equivalent to the predicate device (K240850).

Table 1 Comparison to Predicate -EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Feature: SVS v2 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

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Feature	EPIQ Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
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
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	Smart View Select is an automated software feature that assists you in the selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic examination. This feature automatically classifies each acquired image by view and selects an appropriate set of images for Left ventricle (LV) analysis. The classification is based on a Deep Learning AI interface engine; the selection is a non-AI	Smart View Select is an automated software feature that assists you in the selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic examination. This feature automatically classifies each acquired image by view and selects an appropriate set of images for Left ventricle (LV) analysis. The classification is based on a Deep Learning AI interface engine; the selection is a non-AI	Identical to predicate

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Feature	EPIQ Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
	algorithm that considers the view classification and image depth to select the optimal set of images. You can launch AutoStrain LV or 2D Auto LV with the set of images that have been automatically selected without the need to review the acquired images and manually select the views.	algorithm that considers the view classification and image depth to select the optimal set of images. You can launch AutoStrain LV or 2D Auto LV with the set of images that have been automatically selected without the need to review the acquired images and manually select the views.	
Deep Neural Network Utilization for optimal triplet selection	AI based neural network for optimal view selection	AI based neural network for optimal view selection	The subject SVS software application utilizes a deep neural network for view identification and optimal triplet (A4C, A2C, and A3C) selection for subsequent LV Analysis. The neural network is utilized in a similar way as in the predicate device for the analysis standard 2D echo examinations. The neural network of the subject device was revised as described in attachment 002. Performance testing has demonstrated very strong correlation between the LV analysis outputs (EF, GLS) from clips selected by the subject SVS software application and clips manually selected by clinical users.
Scan depth considered for optimal triplet selection?	Yes – the subject SVS software application uses an additional heuristic logic step, after the deep neural network identifies the views and determines a list of 3 clip combinations (triplets), to preferentially select triplets of shallower scan depths. Restriction of depth on clinical images is 12-20 cm.	Yes – the subject SVS software application uses an additional heuristic logic step, after the deep neural network identifies the views and determines a list of 3 clip combinations (triplets), to preferentially select triplets of shallower scan depths, provided the depth exceeds 10cm and the variation of depths of each clips is 1cm or less.	The subject SVS software application, similar to the predicate device(K240850), includes additional heuristic logic step for preferentially selecting certain scan depths. The logic was revised in the subject device. Performance testing has demonstrated very strong correlation between the LV analysis outputs (EF, GLS) from clips selected by the subject SVS software application and clips manually selected by clinical users. Therefore, the revision in the

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Feature	EPIQ Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
			additional heuristic logic step of the subject SVS software does not raise new or different questions of safety or effectiveness in comparison to the predicate device K240850.

Table 2 Comparison to Predicate - Affiniti

Feature	Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 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), 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.	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	Identical to predicate

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Feature	Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
	Sonography training and clinical procedures are not included in the User Manual or with the Affiniti Series Diagnostic Ultrasound System.	included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System.	
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
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

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Feature	Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
Application Description	Smart View Select is an automated software feature that assists you in the selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic examination. This feature automatically classifies each acquired image by view and selects an appropriate set of images for Left ventricle (LV) analysis. The classification is based on a Deep Learning AI interface engine; the selection is a non-AI algorithm that considers the view classification and image depth to select the optimal set of images. You can launch AutoStrain LV or 2D Auto LV with the set of images that have been automatically selected without the need to review the acquired images and manually select the views.	Smart View Select is an automated software feature that assists you in the selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic examination. This feature automatically classifies each acquired image by view and selects an appropriate set of images for Left ventricle (LV) analysis. The classification is based on a Deep Learning AI interface engine; the selection is a non-AI algorithm that considers the view classification and image depth to select the optimal set of images. You can launch AutoStrain LV or 2D Auto LV with the set of images that have been automatically selected without the need to review the acquired images and manually select the views.	Identical to predicate

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Deep Neural Network Utilization for optimal triplet selection	AI based neural network for optimal view selection	AI based neural network for optimal view selection	The subject SVS software application utilizes a deep neural network for view identification and optimal triplet (A4C, A2C, and A3C) selection for subsequent LV Analysis. The neural network is utilized in a similar way as in the predicate device for the analysis standard 2D echo examinations. The neural network of the subject device was revised as described in attachment 002. Performance testing has demonstrated very strong correlation between the LV analysis outputs (EF, GLS) from clips selected by the subject SVS software application and clips manually selected by clinical users.

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Feature	Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 Proposed Device	EPIQ Series Diagnostic Ultrasound System K240850 Predicate Device	Comparison
Scan depth considered for optimal triplet selection?	Yes – the subject SVS software application uses an additional heuristic logic step, after the deep neural network identifies the views and determines a list of 3 clip combinations (triplets), to preferentially select triplets of shallower scan depths. Restriction of depth on clinical images is 12-20 cm.	Yes – the subject SVS software application uses an additional heuristic logic step, after the deep neural network identifies the views and determines a list of 3 clip combinations (triplets), to preferentially select triplets of shallower scan depths, provided the depth exceeds 10cm and the variation of depths of each clips is 1cm or less.	The subject SVS software application, similar to the predicate device(K240850), includes additional heuristic logic step for preferentially selecting certain scan depths. The logic was revised in the subject device. Performance testing has demonstrated very strong correlation between the LV analysis outputs (EF, GLS) from clips selected by the subject SVS software application and clips manually selected by clinical users. Therefore, the revision in the additional heuristic logic step of the subject SVS software does not raise new or different questions of safety or effectiveness in comparison to the predicate device K240850.

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, including SVS v2 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 and Affiniti Series Diagnostic Ultrasound Systems was tested in accordance with Philips internal procedures. Philips Ultrasound tested the subject devices per the following standards to ensure the continued safe and effective performance:

- IEC 62304 Medical device software – Software life cycle processes, 2006 + A 2015
- 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 introduction of the subject SVS v2 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

In addition, a retrospective data analysis studies were performed to support the substantial equivalence of the SVS v2 features integrated onto EPIQ and Affiniti:

The study was conducted to evaluate the performance of the SVS workflow enhancement algorithm. Three reviewers (clinical experts) participated in the manual selection of clips from subject exam and subsequent semi-automated processing of the clips with AutoStrain LV software to evaluate GLS and EF, which served as ground truth (average across reviewers for each output). The same exams were processed through the SVS software for automatic selection of appropriate clips and subsequent, un-edited evaluation of GLS and EF with AutoStrain LV. GLS and bi-plane EF results for each subject evaluated by the reviewers (averaged across reviewers= ground truth) were compared to the automatically obtained GLS and EF results with SVS selected clips.

The co-primary endpoints for the study were defined as agreements between GLS/EF measured via manual clip selection and compared to SVS clip selection and GLS/EF output using AutoStrain LV software. Agreement was measured as correlation for each output, separately for GLS and EF (co-primary endpoints). A review of the published literature and previous regulatory submissions (K130779, K232500) informed the acceptance criteria for the study to be defined as Lower Confidence Bound for the Pearson's correlation coefficient to be >0.8. In addition to Pearson's correlation assessment, Bland-Altman analysis was performed for EF and GLS

Demographic characteristics data were available from a subset of the study population. The demographic characteristics for this subset of the study population are presented below in the table below.

Table 3: Full demographic and clinical characteristics of patient gathered from US based medical center.

Variable	**mean ± sd (n) (min, max) or %(n/N)**
Sex	
Male	53.5% (38/71)

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Female	46.5% (33/71)
Age (years, mean ± SD (range))	61.0 ± 16.4 (23.0, 89.0)
Height (cm, mean ± SD (range))	171.4 ± 12.1 (145.0, 198.0)
Weight (kg, mean ± SD (range))	87.7 ± 21.4 (47.2, 164.5)
BSA (m^2, mean ± SD (range))	2.0 ± 0.3 (1.4, 2.8)
BMI (kg/m^2, mean ± SD (range))	29.7 ± 6.7 (17.7, 57.6)
Race	
White	35.2% (25/71)
Asian	0.0% (0/71)
Black or African American	60.6% (43/71)
American Indian or Alaska Native	0.0% (0/71)
Native Hawaiian or Other Pacific Islander	0.0% (0/71)
Mixed/More than one race	1.4% (1/71)
Other/Unknown/Not Reported	2.8% (2/71)
LV systolic function	
Normal	46 (64.79%)
Mild	4 (5.63%
Moderate	10 (14.08%)
Severe	11 (15.49%)
RWMA	
Normal	40 (56.34%)
Not Reported	27 (38.03%)
Abnormal	4 (5.63%)
Known CAD	Not Reported
Previous reported MI Location	
None	71 (100.00%)
LV Hypertrophy	
No	42 (59.15%)

Yes	29 (40.85%)

The results of the primary endpoints analysis demonstrate acceptable performance for automatic selection of appropriate clips by SVS software and subsequent output of GLS and EF with AutoStrain LV compared to the results published in literature for EF and GLS. Specifically, for the Pearsons' correlation coefficient was 0.891 (95%CI **0.851**, 0.920) for the EF and 0.906 (95%CI **0.871**, 0.931) for the GLS measurement. The lower confidence bounds were 0.871 for GLS and 0.851 for EF, thereby meeting the predefined acceptance criteria for the study. Taken together, success of the primary endpoint and supporting additional analyses indicate that the safety and effectiveness of the proposed subject software, SVS, is acceptable and aligns with the previously reported performance.

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 SVS v2. 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 SVS v2.

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems with SVS v2 software applications.

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 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.