April 24, 2024

Philips Ultrasound LLC
Michael Chambers
Sr. Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL WA 98021

Re: K240850
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: March 25, 2024
Received: March 27, 2024

Dear Michael Chambers:

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.

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
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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)*

K240850

Device Name

EPIQ Series Diagnostic Ultrasound Systems;
Affiniti Series Diagnostic Ultrasound Systems

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.

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.

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

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be

operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Special 510(k) Summary

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

510(k) Number: K240850

Date Prepared: March 27, 2024

I. Submitter

Manufacturer Name and Address

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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

K233788; Philips EPIQ Series Diagnostic Ultrasound System
K233788; Philips Affiniti Series Diagnostic Ultrasound System

Reference Devices

K212466; LVivo Seamless
K161382; LVivo Software Application with LVivo SG

III. Device Description

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

The Segmental Wall Motion 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 application then provides segmental wall motion scores for each of the 17 segments of the LV by using machine learning algorithms and an overall wall motion score index (WMSI) is calculated as the average of the segmental scores.

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

The SVS feature is supported by all EPIQ models running software version 11.0 or higher including EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, EPIQ 5. The SWM feature is supported by the same EPIQ models running software version VM11.0 or higher, as well as all Affiniti models 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.

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 the introduction

of the SVS or SWM software applications. These 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.

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 introduction of the SWM software application. This software applications 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 introduce the SVS software application feature to the EPIQ Series Diagnostic Ultrasound System and the SWM software application to both EPIQ and Affiniti. The subject device is substantially equivalent to the predicate device (K233788).

Table 1: Comparison to Predicate - EPIQ

Feature	EPIQ Series Diagnostic Ultrasound System Features: SVS and SWM Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Seamless K212466 Reference Device	LVivo Software Application Feature: LVivo SG K161382 Reference 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.	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.	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
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

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Feature	EPIQ Series Diagnostic Ultrasound System Features: SVS and SWM Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Seamless K212466 Reference Device	LVivo Software Application Feature: LVivo SG K161382 Reference Device	Comparison
USA FDA Classification	Class II	Class II	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	QIH	LLZ	Identical to predicate
Primary Regulation Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Automated Radiological Image Processing Software	Medical image management and processing system.	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)	N/A, software-only	N/A, software-only	Identical to predicate
Device Track	Track 3	Track 3	N/A, software-only	N/A, software-only	Identical to predicate
Application Description	Smart View Select is an automated software feature that assists the user in selection of images for analysis with the existing Philips AutoStrain LV or 2D Auto LV application in Adult Echo Transthoracic (TTE) examination. The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. Note: Per FDA Guidance Technical	The predicate EPIQ Series Diagnostic Ultrasound System does not currently have a dedicated software application containing the functionality introduced in the subject submission for (1) automatic selection of 4CH,2CH, and 3CH views for left ventricle (LV) analysis or (2) (semi-) automated segmental wall motion evaluation of the left ventricle (LV).	The LVivoSeamless software is a standalone application that extends the LVivo Platform and runs offline on a server. The system accepts echo examination that are sent from the US device using DICOM communication. The examinations contain clips in DICOM format. The LVivoSeamless scans the entire examination and selects automatically 4CH,2CH and 3CH views for EF and GLS evaluation and runs the LVivoEF and the LVivoStrain. The	The LVivoSG is a decision support system (software) for automated segmental wall motion evaluation of the left ventricle (LV). The LVivoSG is based on a proprietary algorithm for LV regional motion parameters calculation and wall motion classification. The LVivoSG uses the LVivo platform to detect the LV inner borders (endocard) from which the wall motion parameters are calculated. As part of the LVivoSG development, the LVivo	The subject EPIQ Series Diagnostic Ultrasound System integrates the LVivo Seamless algorithm of the K212466 reference device as “Smart View Select” and the LVivo SWM module of the LVivo SG K161382 reference device as “Segmental Wall Motion”. Minor changes have been made to the reference LVivo Seamless and LVivo SG software applications in the subject SVS and SWM applications, as described below.

Feature	EPIQ Series Diagnostic Ultrasound System Features: SVS and SWM Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Seamless K212466 Reference Device	LVivo Software Application Feature: LVivo SG K161382 Reference Device	Comparison
	Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions, the SWM software is a semi-automated quantitative imaging algorithm, as users are generally expected to review and concur with the initialization and generated results. The users can also edit algorithm generated segmental wall motion scores for individual segments based on their clinical expertise.		results are sent back using DICOM communication to the PACS server and become part of the study. The clinician that reviews the examinations at the PACS workstation will be able view the output of the LVivoEF and LVivoStrain as part of the study review.	platform supports also edge detection and tracking in additional plane, the apical long (3CH). The LVivoSG provides fully automated measurements of the regional left ventricular systolic function from three apical views the four chamber (4CH), two chamber (2CH) and long (3CH).	
Deep Neural Network utilized for optimal triplet selection	LVivo Seamless AI neural network	Not applicable – does not contain functionality for optimal triplet selection	LVivo Seamless AI neural network	Not applicable – does not contain functionality for optimal triplet selection	The subject SVS software application utilizes the identical, unchanged deep neural network for view identification and optimal triplet (A4C, A2C, and A3C) selection for subsequent LV analysis
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, provided the depth exceeds 10cm and the variation of depths of each clips is 1cm or less	Not applicable – does not contain functionality for optimal triplet selection	Not applicable – scan depth is not considered in the selection of the optimal triplets for the user	Not applicable – does not contain functionality for optimal triplet selection	The subject SVS software application adds an additional heuristic logic step for preferentially selecting certain scan depths from the reference LVivo Seamless. The Neural Network of the reference device is unchanged, as described above. 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 additional heuristic logic step of the subject SVS software does not raise new or different questions of safety or effectiveness in comparison to the reference device K212466.
Border initialization algorithm(s) utilized for segmental wall motion	Primary – from K161382 Secondary – from cleared AutoStrain LV (K190913)	Not applicable – does not contain functionality for segmental wall motion	Not applicable – this application does not contain functionality for segmental wall motion	From K161382	Subject device preferentially utilizes identical border initialization algorithm as reference device K161382. If the reference device's algorithm is unsuccessful in the subject SWM, it will use

Feature	EPIQ Series Diagnostic Ultrasound System Features: SVS and SWM Proposed Device	EPIQ Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Seamless K212466 Reference Device	LVivo Software Application Feature: LVivo SG K161382 Reference Device	Comparison
					the border initialization of the cleared AutoStrain LV (K190913) as a back-up. Performance testing has demonstrated very strong correlation between the SWM scoring of the subject software application compared to the scoring of the reference device on the same clips. Therefore, there are no new or increased risks for the use of the AutoStrain LV border initialization in the subject SWM software application as a back-up.
SWM scoring adjustment	Users manually edit scores using a drop-down selection	Not applicable – does not contain functionality for segmental wall motion	Not applicable – this application does not contain functionality for segmental wall motion	Users must manually edit the borders to attempt to edit scores	In the cleared LVivo SG, users must manually adjust the chamber borders to influence the SWM scores. In the subject SWM on VM11, users may manually select different SWM scores for each segment using a drop-down menu. Any scores which are manually changed from those calculated by the software application will be indicated by an asterisk (*). This change in editing does not introduce new risks because it is providing a simpler way for the user to edit their segmental wall motion score(s) – instead of having to edit the border contours to influence the SWM score as on the cleared LVivo SG, user can directly edit each segment's score with the drop-down.

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Table 2: Comparison to Predicate - Affiniti

Feature	Affiniti Series Diagnostic Ultrasound System Feature: SWM Proposed Device	Affiniti Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Software Application Feature: LVivo SG K161382 Reference 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.	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.	Identical to predicate
Intended Users	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the Affiniti Series Diagnostic Ultrasound System.	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the Affiniti Series Diagnostic Ultrasound System.	Trained healthcare professionals	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.	Professional healthcare environments	Identical to predicate
USA FDA Classification	Class II	Class II	Class II	Identical to predicate
Primary Product Code	IYN	IYN	LLZ	Identical to predicate
Primary Regulation Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Medical image management and processing system.	Identical to predicate
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.2050	Identical to predicate
Secondary Product Codes	ITX IYO OBJ QIH	ITX IYO OBJ QIH	N/A	Identical to predicate
Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter	N/A	Identical to predicate

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Feature	Affiniti Series Diagnostic Ultrasound System Feature: SWM Proposed Device	Affiniti Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Software Application Feature: LVivo SG K161382 Reference Device	Comparison
	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software		
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	Identical to predicate
Reusable-Systems and Transducers	Yes	Yes	No, software-only	Identical to predicate
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	N/A, software-only	Identical to predicate
Device Track	Track 3	Track 3	N/A, software-only	Identical to predicate
Application Description	The SWM software automatically evaluates the segmental (regional) function of the left ventricle (LV) from adult TTE echo examinations. Note: Per FDA Guidance Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions, the SWM software is a semi-automated quantitative imaging algorithm, as users are generally expected to review and concur with the initialization and generated results. The users can also edit algorithm generated segmental wall motion scores for individual segments based on their clinical expertise.	The predicate Affiniti Series Diagnostic Ultrasound System does not currently have a dedicated software application containing the functionality introduced in the subject submission for (semi-) automated segmental wall motion evaluation of the left ventricle (LV).	The LVivoSG is a decision support system (software) for automated segmental wall motion evaluation of the left ventricle (LV). The LVivoSG is based on a proprietary algorithm for LV regional motion parameters calculation and wall motion classification. The LVivoSG uses the LVivo platform to detect the LV inner borders (endocard) from which the wall motion parameters are calculated. As part of the LVivoSG development, the LVivo platform supports also edge detection and tracking in additional plane, the apical long (3CH). The LVivoSG provides fully automated measurements of the regional left ventricular systolic function from three apical views the four chamber (4CH), two chamber (2CH) and long (3CH).	The subject Affiniti Series Diagnostic Ultrasound System integrates the LVivo SWM module of the LVivo SG K161382 reference device as “Segmental Wall Motion”. The subject SWM software application utilizes the border initialization of the cleared AutoStrain LV software in the event that the border initialization algorithm from LVivo SG is unsuccessful. Otherwise, there is no difference between the subject SWM software application and the reference LVivo SG’s SWM module and no changes have been made to its algorithms.
Border initialization algorithm(s) utilized for segmental wall motion	Primary – from K161382 Secondary – from cleared AutoStrain LV (K190913)	Not applicable – does not contain functionality for segmental wall motion	From K161382	Subject device preferentially utilizes identical border initialization algorithm as reference device K161382. If the reference device’s algorithm is unsuccessful in the subject SWM, it will use the border initialization of the cleared AutoStrain LV (K190913) as a back-up. Performance testing has demonstrated very strong correlation between the SWM scoring of the subject software application compared to the scoring of the reference device on the same clips. Therefore, there are no new or increased risks for the use of the AutoStrain LV border initialization in the subject

Feature	Affiniti Series Diagnostic Ultrasound System Feature: SWM Proposed Device	Affiniti Series Diagnostic Ultrasound System K233788 Predicate Device	LVivo Software Application Feature: LVivo SG K161382 Reference Device	Comparison
				SWM software application as a back-up.
SWM scoring adjustment	Users manually edit scores using a drop-down selection	Not applicable – does not contain functionality for segmental wall motion	Users must manually edit the borders to attempt to edit scores	In the cleared LVivo SG, users must manually adjust the chamber borders to influence the SWM scores. In the subject SWM on VM11, users may manually select different SWM scores for each segment using a drop-down menu. Any scores which are manually changed from those calculated by the software application will be indicated by an asterisk (*). This change in editing does not introduce new risks because it is providing a simpler way for the user to edit their segmental wall motion score(s) – instead of having to edit the border contours to influence the SWM score as on the cleared LVivo SG, user can directly edit each segment's score with the drop-down.

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, including SVS and SWM 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 and SWM 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, two retrospective data analysis studies were performed to support the substantial equivalence of the SVS and SWM features integrated onto EPIQ and Affiniti:

The first 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.

The results of the co-primary endpoints analysis demonstrated very strong correlation for GLS and EF outputs when manually selected clips were compared to SVS selected clips for the same subject exams. Specifically, for the Pearsons' correlation coefficient was 0.911 (95%CI 0.855,0.946) and 0.941 (95%CI 0.903,0.965), for GLS and EF, respectively. The lower confidence bounds were 0.855 for GLS and 0.903 for EF, thereby meeting the predefined acceptance criteria for the study.

A separate study was conducted to assess the use of Segmental Wall Motion (SWM), a machine learning-based feature in quantification of Wall Motion Score Index (WMSI) in transthoracic (TTE) ultrasound clips obtained from subjects referred for clinical TTE exam. The study evaluated the performance of the integrated SWM algorithm compared to LVivo SWM (DiA Imaging Analysis) application (ground truth) in the quantification of WMSI for the same subjects' exams. The study was executed in 2 phases with a 7-day washout period between the phases. In phase 1, three reviewers (clinical experts) participated in the manual selection of representative clips from subject TTE exams and subsequent processing of the clips with LVivo application for WMSI output, which served as ground truth in the study (average across reviewers). In phase 2, the manually selected clips as well as SVS selected clips (clips selected by the SVS workflow algorithm from subject exams used in phase1) were processed by the same 3 reviewers with the integrated (subject) SWM algorithm for WMSI output, in a random order.

A review of published literature within the cardiac assessment space and previous regulatory submissions (K130779, K223771, 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 for each endpoint. Acceptance criteria were defined prior to study execution.

The results of the co-primary endpoints analysis demonstrated very strong correlation for manual and SVS selected clips and assessed for WMSI of the subject SWM algorithm when compared to the ground truth. Specifically, the Pearsons' correlation coefficient was 0.957 (95%CI 0.933,0.972) and 0.913 (95%CI 0.857,0.948), for the manual and SVS workflows, respectively. The lower confidence bounds were 0.933 for manual workflow and 0.857 for SVS workflow, thereby meeting the predefined acceptance criteria for the study.

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 and SWM. 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 and SWM.

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VIII. Clinical Data

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