July 24, 2025

Philips Ultrasound LLC
Patricia Beauregard
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K251455
Trade/Device Name: EPIQ Series Diagnostic Ultrasound System; Affiniti Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH, OBJ
Dated: June 24, 2025
Received: June 24, 2025

Dear Patricia Beauregard:

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.	K251455

Please provide the device trade name(s).

EPIQ Series Diagnostic Ultrasound System;
Affiniti Series Diagnostic Ultrasound System

Please provide your Indications for Use below.

EPIQ:
The intended use of EPIQ Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:
Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), intra-luminal, intra-cardiac echo, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.
Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.
The clinical environments where EPIQ Series Diagnostic ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.
When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.
The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Affiniti:
The intended use of Affiniti Series Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:
Abdominal, Cardiac Adult, Cardiac Other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.
Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.
The clinical environments where the Affiniti diagnostic ultrasound systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients. The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Please select the types of uses (select one or both, as applicable).	☒ 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: K251455

Date Prepared: July 23, 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

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
Catheter, Ultrasound, Intravascular	870.1200	OBJ*

*EPIQ only

Reference Device: K243235, LVivo Application (Auto EF Feature)

Device & Classification Name: Medical Image Management and Processing System – classified as Class 2 QIH, Regulation Number 21 CFR 892.2050 LVivo Software Application

III. Device Description

The purpose of this 510(k) Pre-market Notification is to introduce the SVS v2 Contrast software application with the EPIQ and Affiniti Series Diagnostic Ultrasound Systems as part of the VM13.0 program.

SVS v2 Contrast is an automated software feature that assists in the selection of images for analysis with the new Philips license options 2D Auto EF Advanced (Adv) developed by DiA Imaging Analysis (K243235), now part of Philips Ultrasound LLC, and existing Philips license options AutoStrain LV; or 2D Auto LV (both K240850) license application in Adult Echo Transthoracic (TTE) examinations.

As described in 510(k) K240850, 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 inference engine; the selection is a non-AI algorithm that considers the view classification and image depth to select the optimal set of images. The difference in SVS v2 Contrast from the predicate SVS v1 (K240850) is that the algorithm is revised to include the selection of optimal images for analysis when contrast is used in routine TTE exams.

Users can launch existing 2D Auto EF; 2D Auto EF Adv; 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. Users may select 2D Auto EF Adv, to process the selected views by SVS v2 Contrast. SVS v2 Contrast prioritizes the contrast image pair; however, if an appropriate pair of contrast images is not found, then Auto EF Adv may select non-contrast images. The manual approach to select views is still available and the user can override automatically selected images from SVS v2 Contrast.

No hardware changes to the EPIQ or Affiniti Series Diagnostic Ultrasound Systems are required when using SVS v2 Contrast, and existing, cleared Philips TTE transducers.

The SVS v2 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. The SVS v2 Contrast 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 v2 Contrast feature is 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 and Harmonic Imaging.

The clinical environments where EPIQ Series Diagnostic ultrasound Systems can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live echo guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety

procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

Note: There are no changes to the EPIQ Ultrasound System Indications for Use due to the modification of the SVS v2 Contrast software application. This software application is 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 and Harmonic Imaging.

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

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

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

Note: There are no changes to the Affiniti Ultrasound System Indications for Use due to the modification of the SVS v2 Contrast 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 introduce the SVS v2 software application feature with SVS v2 Contrast to both the EPIQ and Affiniti Series Diagnostic Ultrasound Systems. The subject devices are substantially equivalent to the predicate devices (K240850).

Feature	EPIQ & Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 Contrast Proposed Device	EPIQ & Affiniti Series Diagnostic Ultrasound Systems K240850 Predicate Device	LVivo Software Application Feature: Auto EF K243235 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. In addition, it has the ability to provide Quality Score feedback	No change
Intended Users	Trained healthcare professionals Intended for sonographers, physicians 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 and Affiniti Series Diagnostic Ultrasound System.	Trained healthcare professionals Intended for sonographers, physicians 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 and Affiniti Series Diagnostic Ultrasound System.	Trained healthcare professionals	No change
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	No change
USA FDA Classification	Class II	Class II	Class II	No change
Primary Product Code	IYN	IYN	QIH	No change
Primary Regulation Name	Ultrasonic pulsed doppler imaging system	Ultrasonic pulsed doppler imaging system	Medical image management and processing system	No change
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.2050	No change

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Feature	EPIQ & Affiniti Series Diagnostic Ultrasound System Feature: SVS v2 Contrast Proposed Device	EPIQ & Affiniti Series Diagnostic Ultrasound Systems K240850 Predicate Device	LVivo Software Application Feature: Auto EF K243235 Reference Device	Comparison
Secondary Product Codes	ITX IYO OBJ QIH	ITX IYO OBJ QIH	N/A	No change
Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Medical image management and processing system	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Medical image management and processing system	N/A	No change
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	No change
Reusable-Systems and Transducers	Yes	Yes	No, software-feature	No change
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	N/A, software-feature	No change
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 (K240850) application in Adult Echo Transthoracic (TTE) examination. Users can launch existing 2D Auto EF; 2D Auto EF Adv (submitted K251110) or AutoStrain LV; or 2D Auto LV (both K240850) with the set of images that have been automatically selected without the need to review the acquired images and manually select the views. Users may select 2D Auto EF Adv, to process the selected views by SVS v2 Contrast. SVS v2 Contrast prioritizes the contrast image pair; however, if an appropriate pair of contrast images is not found, then Auto EF Adv may select non-contrast images. The manual approach to select views is still available and the user can override automatically selected images from SVS v2 Contrast.	Predicate integrates the LVivo seamless algorithm (K212466) to introduce Smart View Select (SVS) on the EPIQ Series Diagnostic Ultrasound System. SVS is an automated software feature that assists the user in selection of optimal images for analysis with the existing Pillips AutoStrain LV or 2D Auto LV (both K240850) The LVivo contains the functionality introduced 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).	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 diseases. In addition, it has the ability to provide Quality Score feedback	The algorithm is revised to include the selection of optimal images for analysis when contrast is used in routine TTE exams.
Deep Neural Network	LVivo Seamless AI neural network	LVivo Seamless AI neural network	LVivo Seamless AI neural network	No change

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, including SVS v2 Contrast software application, and compatible transducers are all Track 3 Devices and comply with the referenced standards as well as the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (*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 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

In addition, a retrospective data study, utilizing previously acquired exams (including contrast and non-contrast clips) with TTE transducers, was conducted to evaluate the performance of SVS v2 Contrast workflow.
To ensure data separation between development and testing data, the data set to which each exam belongs was identified.
The study was conducted as a sub analysis of the data used for FDA (K240850) on ultrasound examination acquired with Philips ultrasound systems.

One sonographer (reviewer) participated in the manual selection of clips from subject exams, which were subsequently automatically processed within Contrast EF application for EF output. The automated EF results from processing manually selected contrast clips served as ground truth. The ground truth was generated as part of K243235 submission. Additionally, the manually selected clips were measured by 3 sonographers following a physicians review. This clinical ground truth was also created as part of K243235. The same exams were processed through the SVS v2 Contrast workflow for automatic selection of appropriate clips and subsequent output of EF within the Contrast EF application

The automatically calculated Biplane EF and the Biplane EF calculated by manual tracing as the ground truth were compared to the automatically obtained Biplane EF results with SVS selected clips. The primary endpoint for the study was the correlation between Biplane EF measured via manual contrast clip selection and compared to auto (SVS) contrast clip selection and Biplane EF output. A review of the published literature[1] 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.

[1] Maret, E. B. (2008). Computer-assisted determination of left ventricular endocardial borders reduces variability in the echocardiographic assessment of ejection fraction. *Cardiovascular Ultrasound*, 6(1), 1-14.

Results:

The results from the primary endpoint assessment

Table 1. Primary Endpoint:
Pearson's correlation analysis for Biplane EF – SVS Selected (Automated) vs Biplane EF - Manually Selected (Ground Truth)

Outcomes Comparison	N	Pearson's correlation coefficient (r) (95% CI)	p-value
Biplane EF - SVS Selected (Automated) vs Biplane EF - Manually Selected (Ground Truth)	46	0.953 (**0.917**, 0.974)	<.0001

In addition, Bland-Altman analysis was performed for automatic selection of appropriate clips by the SVS software and subsequent output of Biplane EF with SVS compared to the results of the Biplane EF from manually selected contrast clips served as ground truth. The data are presented in Table 2.

Table 2. Primary Endpoint: Agreement Assessment by Bland-Altman Analysis for Biplane EF - SVS (Automated) vs Biplane EF - Manually Selected (Ground Truth)

Outcomes Comparison	Mean Difference ± SD (n)	95 % CI for Mean Difference	Lower LoA (95% CI)	Upper LoA (95% CI)
EF - SVS Selected (Automated) vs EF - Manually Selected (Ground Truth)	0.71 ± 4.36 (46)	-0.58 , 2.01	-7.83 (-10.06, -5.60)	9.26 (7.03, 11.49)

Table 3. Pearson's correlation analysis for Biplane EF – SVS Selected (Automated) vs Biplane EF – by Manual Tracing (Ground Truth)

Outcomes Comparison	N	Pearson's correlation coefficient (r) (95% CI)	p-Value
EF–SVS Selected (Automated) vs EF–Manually Tracing (Ground Truth)	46	0.938 (0.890, 0.965)	<.0001

Table 4. Agreement Assessment by Bland-Altman Analysis for Biplane EF - SVS (Automated) vs Biplane EF – Manual Tracing (Ground Truth)

Outcomes Comparison	Mean Difference ± SD (n)	95 % CI for Mean Difference	Lower LoA (95% CI)	Upper LoA (95% CI)
EF - SVS Selected (Automated) vs EF - Manually Tracing (Ground Truth)	1.22 ± 5.22 (46)	-0.33, 2.77	-9.01 (-11.67, -6.34)	11.45 (8.78, 14.11)

A total of 60 subjects were in the initial cohort for the study. The study sample size was 56, with 10 samples being non-reportable.. The evaluable study sample included a total of 46 subjects. Gender data was available for 53(88.3%) of the patients. 20/53 (37.7%) were female and 33/53 (62.3%) were male. Age ranged from 20 to 87 years of age.

For 7 patient exams collected from first site outside USA, the average age was 64±10.6 years old. For the second site in the USA, the average age was 63±15.8 years old, average BMI was 31.9±8, range 17.9 to 54.

Race information was available for total of 47/53 (88.7%) patient examinations collected from USA, among them 19/47 (40.4%) were indicated as Black or African Americans, 20/47 (42.6%) were indicated as white, and 2/47 (4.26%) were Asian and 6/47(12.8%) had unknown race information.

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Pearson's correlation analysis for EF by AutoEF Contrast – SVS Selected clips (Automated) vs EF by AutoEF Contrast on Manually Selected clips (Ground Truth) stratified by demographics and systolic function (n=46)

Outcomes Comparison	N	Pearson's correlation coefficient (r) (95% CI)
Gender		
Male	32	0.943 (0.885, 0.972)
Female	14	0.973 (0.915, 0.992)
Systolic Function		
Normal	24	0.926 (0.833, 0.968)
Abnormal	22	0.923 (0.822, 0.968)

Conclusions:

As shown in **Table 1**, the acceptance criteria for the primary endpoint were met, specifically the Pearson's correlation coefficient and associated confidence intervals are 0.953 (95% CI 0.917, 0.974) for the Biplane EF measurement. The results presented above in **Table 2** for Bland-Altman agreement demonstrate acceptable performance for automatic selection of appropriate clips by SVS software and subsequent output of Contrast Enhanced Biplane EF feature (which is part of the VM13 release, and the 2D Auto EF Adv product) compared to the results of Contrast Enhanced Biplane EF from manually selected contrast clips which severed as ground truth. 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.

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 Contrast software application.

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 and supports 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.