February 13, 2024

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

Re: K233788
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, OBJ, QIH
Dated: November 17, 2023
Received: November 28, 2023

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
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233788

Device Name

EPIQ Series Diagnostic Ultrasound System;
Affiniti Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

EPIQ:

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

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

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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I. 510(k) Summary

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

510(k) Number: K233788

Date Prepared: February 13, 2024

II. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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III. 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*

*Applicable only to Philips EPIQ Series Diagnostic Ultrasound System, per clearance under K202216; Not applicable for Philips Affiniti Series Diagnostic Ultrasound System

Device Class

Class II

Review Panel

Radiology

Predicate Device

K211597; Philips EPIQ Series Diagnostic Ultrasound System
K211597; Philips Affiniti Series Diagnostic Ultrasound System

Reference Device

K231190; Philips EPIQ Series Diagnostic Ultrasound System

IV. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the Smart Doppler View ID software feature onto the EPIQ and Affiniti Series Diagnostic Ultrasound Systems.

The purpose of the Smart Doppler View ID feature is to enhance the user's workflow through providing automation of the navigation of the touch screen groups on the Ultrasound System associated with Doppler Measurements. Without the Smart Doppler View ID feature, users must manually navigate to the desired Doppler Calculation Package Group on the Ultrasound System's various screens to perform a measurement. The Smart Doppler View ID feature automates this navigation and selects the associated calculation package group for the user based on the provided Doppler Spectrum acquired by the user using an artificial intelligence–based algorithm.

Smart Doppler View ID maps to six Doppler Calculations Package groups on the Ultrasound System screen:

- Aortic Valve
- Mitral Valve
- Tricuspid Valve
- Pulmonic Valve
- Venous Flow
- TDI Vel (Tissue Doppler Imaging Velocity) & Ratio

No hardware changes to the EPIQ or Affiniti systems are required when using the Smart Doppler View ID feature, and existing, commercialized Philips transducers are used for the Smart Doppler View ID feature.

The feature is supported by all EPIQ and Affiniti models running software version 11.0 or higher including EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, EPIQ 5, Affiniti CVx, Affiniti 70, Affiniti 50, and Affiniti 30. The Smart Doppler View ID feature is associated with the cardiac adult indication.

V. 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 Smart Doppler View ID feature. The Smart Doppler View ID 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.

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 Smart Doppler View ID feature. The Smart Doppler View ID is associated with the Cardiac Adult indication.

VI. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the Smart Doppler View ID feature to the EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System. The subject devices are substantially equivalent to the predicate devices (K211597) and reference device (K231190).

Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Proposed Devices	Philips EPIQ Series Diagnostic Ultrasound System Affiniti Diagnostic Ultrasound System (K211597) Predicate Devices	Philips EPIQ Series Diagnostic Ultrasound System (K231190) Reference Device	Comparison
USA FDA Classification	Class II	Class II	Class II	Identical
Primary Product Code	IYN	IYN	IYN	Identical
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.1550	Identical
Marketing Name of Application	Smart Doppler View ID	Not applicable since the application is new	Not applicable since the application is new	Subject of this submission

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Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Proposed Devices	Philips EPIQ Series Diagnostic Ultrasound System Affiniti Diagnostic Ultrasound System (K211597) Predicate Devices	Philips EPIQ Series Diagnostic Ultrasound System (K231190) Reference Device	Comparison
Application Description	The proposed Smart Doppler View ID feature is intended to be used Adult Cardiology Transthoracic examinations to automate the navigation of the Calculations Package group associated with Doppler Measurements. Without the Smart Doppler View ID feature, users must manually navigate to the desired Doppler Calculations Package Group on the Ultrasound System to perform a measurement. The Smart Doppler View ID feature automates this navigation and selects the associated Calculations Package group for the user based on the provided Doppler Spectrum acquired by the user. Automated selection of Calculation Package Groups by Smart Doppler View ID: • Aortic Valve • Mitral Valve • Tricuspid Valve • Pulmonic Valve • Venous Flow • TDI Vel & Ratio	Manual selection by the user of Calculations Package group on the ultrasound system associated with measurement groups on the ultrasound system. Manual selection of Calculation Package Groups by the user: • Aortic Valve • Mitral Valve • Tricuspid Valve • Pulmonic Valve • Venous Flow • TDI Vel & Ratio	Manual selection by the user of Calculations Package group on the ultrasound system associated with measurement groups on the ultrasound system. Manual selection of Calculation Package Groups by the user: • Aortic Valve • Mitral Valve • Tricuspid Valve • Pulmonic Valve • Venous Flow • TDI Vel & Ratio	Subject of this submission. The Smart Doppler View ID automates the selection of Calculations Package group on the ultrasound system during Adult Cardiology Transthoracic examinations, where the predicate and reference devices require users to manually navigate to their desired Calculations Package group to perform subsequent measurements. The Smart Doppler View ID feature does not perform any measurements itself and is only intended to automate the selection of the Calculations Package group associated with an acquired doppler spectrum. There is no change to the Calculation Package Groups available to the user.
User Interface Presentation	After a user acquires a doppler spectrum, a Calculations Package group is automatically highlighted on the ultrasound system display for the user by Smart Doppler View ID. From the highlighted Calculations Package group, the user may select a desired measurement to perform on the image. If the user disagrees with the highlighted Calculations Package group, they can manually navigate to their desired Calculations Package group.	After a user acquires a doppler spectrum, the user must manually navigate to the desired Calculations Package group. From the manually selected Calculations Package group, the user may select a desired measurement to perform on the image.	After a user acquires a doppler spectrum, the user must manually navigate to the desired Calculations Package group. From the manually selected Calculations Package group, the user may select a desired measurement to perform on the image.	The only difference with Smart Doppler View ID is that the Measurement Calculations Package group is automatically highlighted for the user after a doppler spectrum is acquired. Without Smart Doppler View ID, users must manually navigate to their desired Calculations Package group. There is no change to the user's functionality once the Calculations Package group is selected for them compared to their workflow without Doppler View ID.

Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Proposed Devices	Philips EPIQ Series Diagnostic Ultrasound System Affiniti Diagnostic Ultrasound System (K211597) Predicate Devices	Philips EPIQ Series Diagnostic Ultrasound System (K231190) Reference Device	Comparison
Compatible transducers	**EPIQ:** X5-1, X5-1c, and S5-1 are already commercially available and compatible with the EPIQ Ultrasound System. **Affiniti:** S5-1, X5-1, and S4-2 are already commercially available and compatible with the Affiniti Ultrasound System. No new transducers. Transducer modes for Smart Doppler View ID: 2D, PWD, CWD, TDI. No new transducer modes.	No new transducers and no new modes	The K231190 submission introduced the mL26-8 transducer. This transducer is not compatible with the proposed Smart Doppler View ID feature.	No new transducers or modes are being introduced in this submission. All transducers are already available with the EPIQ and Affiniti Ultrasound Systems.
Measurements Performed	No measurements are performed by the Smart Doppler View ID feature. Any cardiac adult TTE measurements resulting from the view selection are performed either manually by the user or by the commercially available AutoMeasure function (K211597).	Any cardiac adult TTE measurements resulting from the view selection are performed either manually by the user or by the commercially available AutoMeasure function (K211597).	Any cardiac adult TTE measurements resulting from the view selection are performed either manually by the user or by the commercially available AutoMeasure function (K211597)	No new measurements are being introduced in this submission. The subject of this submission is to provide workflow enhancements using an artificial intelligence - application.
Application performance	Algorithm accuracy of 97.5% (95%CI 96.3%, 98.3%), p-value <0.0001 compared to the ground truth	N/A – the equivalent functionality is performed manually by users to select the appropriate calculation package group (touch screen group)	N/A – the equivalent functionality is performed manually by users to select the appropriate calculation package group (touch screen group)	Subject of this submission

VII. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System, including Smart Doppler View ID feature, 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.

VIII. Nonclinical Performance Data

The proposed modification of the EPIQ Series 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
- 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 software algorithm for the Smart Doppler View ID

software feature. The activities to assure the safe and effective performance of the software revision included, but are not limited to, the following:

- Requirements Review
- Risk Analysis and Management Review
- Product Specification Review
- Design Reviews

Non-Clinical Verification Testing of requirements, consisted of feature-specific functional testing, transducer compatibility, user interface and workflow testing related to Smart Doppler View ID Software Feature introduced in this submission as part of the software verification activities for the system and for X5-1, S5-1, X5-1c, and S4-2 transducers supporting the Smart Doppler View ID Software feature.

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 Smart Doppler View ID. 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 Smart Doppler View ID.

IX. Clinical Data

Summary of Clinical Tests

There was no clinical investigation needed for this premarket submission of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems with Smart Doppler View ID feature, which is an artificial intelligence-based feature.

Artificial Intelligence Summary

The Smart Doppler View ID algorithm is an Artificial Intelligence (AI) based tool that automates the navigation of the touch screen groups on the Ultrasound System associated with Doppler Measurements.

A study was conducted to evaluate the performance of the new algorithm, where 1100 previously collected TTE (transthoracic echo) cardiac clips acquired with doppler mode from 400 subject videos were processed through the Smart Doppler View ID algorithm and its output (touch screens) compared to Standard of Care obtained group of measurements (touch screens). The Standard of Care measurements are those measurements recommended by the American Society of Echocardiography (ASE) guidelines for routine TTE cardiac exams. The data used for the clinical performance study were completely distinct from that used during training of the algorithm, and there was no overlap between the two data sets.

The primary endpoint was accuracy between Smart Doppler View ID and ground truth. The Ground truth for the study was based on a group of measurements performed by intended users (i.e., Board certified cardiologists and cardiac sonographers) of the Ultrasound Systems as part of Standard of Care TTE exam per ASE guidelines at a large US-based hospital. The Ground truth (touch screen) was determined on a set of measurements performed on acquired Doppler waveforms and mapped to touch screens (i.e., a Power Doppler Waveform acquired to measure the mitral valve inflow is mapped to the Mitral Valve Touch Screen group). All of the Doppler TTE clips included in the ground truthing were acquired by the 16 cardiac sonographers with a high level of expertise, and all these studies have been vetted and interpreted by Board certified cardiologists that have successfully passed the National Board of Echocardiography Examination. Accuracy was evaluated by comparing the ground truth touch screens and Smart Doppler View ID auto-detected touch screen for the same TTE clips as outputted by the algorithm.

Dataset

Subjects from whom the study data were sampled had presented to a USA-based hospital und

underwent routine TTE adult cardiac exam. Overall, 400 subjects contributed 1100 clips evaluated in this study. The touchscreen distribution in the study closely resembled the anticipated clinical distribution based on typical measurements performed as part of standard of care TTE cardiac assessment exams as recommended by the American Society of Echocardiography (ASE) guidelines. Moreover, subjects whose clips contributed to the study represented a broad range of demographics and body habitus, representative of the intended population.

The demographic distribution of the study population includes the following:

Demographic	Result (N=400) (% (xx/N)
Sex	
Female	56.3% (225/400)
Male	43.8% (175/400)
Age (years, mean ± SD (range))	61.9 ± 16.6 (18.4, 98.7)
Height (cm, mean ± SD (range))	169.2 ± 10.7 (125,196)
Weight (kg, mean ± SD (range))	84.2 ± 23.7 (40.8, 263.0)
BSA (m^2, mean ± SD (range))	1.9 ± 0.3 (1.3, 3.4)
BMI (kg/m^2, mean ± SD (range))	29.5 ± 7.8 (15.8,78.5)
Race	
White	31.3% (125/400)
Asian	2.8% (11/400)
Black or African American	53.8% (215/400)
American Indian or Alaska Native	0.3% (1/400)
Native Hawaiian or Other Pacific Islander	0.8% (3/400)
Mixed/More than one race	9.5% (38/400)
Other/Unknown/Not Reported	1.8% (7/400)

Results

The results of the primary endpoint analysis demonstrated algorithm accuracy of 97.5% (95%CI 96.3%, 98.3%), p-value <0.0001, thereby meeting the acceptance criteria for the study.

Conclusion

The results of the study demonstrated clinically reasonable, relevant and meaningful performance of the Smart Doppler View ID algorithm in supporting clinicians' workflow by automatically detecting touchscreens during adult cardiac TTE exams with doppler mode. Specifically, success on the primary endpoint of accuracy indicates that the safety and effectiveness of the proposed algorithm is acceptable. Lastly, the algorithm workflow allows users to adjust the touchscreen outputs, if necessary.

X. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

XI. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject devices meets their intended use.

The changes made to the subject devices do not affect the use of the devices, nor do they introduce any new or significantly modified risks. The results of the relevant performance and compatibility tests support a determination that the proposed subject devices do not raise new questions of safety or effectiveness.

Therefore, the subject devices are substantially equivalent to the predicate and reference devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.