



November 15, 2024

Philips Ultrasound LLC
Suresh Kumar Alagarsamy
Senior Specialist I - Regulatory Affairs
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K242800
Trade/Device Name: The 5000 Compact Series 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
Dated: September 16, 2024
Received: September 17, 2024

Dear Suresh Kumar Alagarsamy:

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

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OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K242800

Device Name

The 5000 Compact Series Ultrasound Systems

Indications for Use (Describe)

The intended use of the 5000 Compact series ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: Abdominal, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal Echo, Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Pediatric, Peripheral Vessel, Small Parts, Transesophageal (Cardiac), Transrectal, Transvaginal, and Urology.

The clinical environments where the systems can be used include physicians' offices, clinics, hospitals, surgical suites, and clinical point-of-care for diagnosis of patients. The System is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed.

However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

510(k) Number: **K242800**

Date Prepared: September 16, 2024

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	Suresh Kumar Alagarsamy Senior Specialist I – Regulatory Affairs 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA +91 97401 63840
Secondary Contact	Erdit Gremi Director, Regulatory Affairs – Software & AI 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA 1-617-798-8092

II. Device

Proprietary Name	5000 Compact Series Ultrasound Systems Auto Measure		
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
Device Class	Class II		
Review Panel	Radiology		
Predicate Device	K222648 5000 Compact Series Diagnostic Ultrasound Systems		
Reference Device	K211597 Philips Affiniti Series Diagnostic Ultrasound System VM 9.0		

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the Auto Measure Artificial Intelligence-Machine Learning software feature onto the 5000 Compact Series Ultrasound Systems.

The Auto Measure feature utilizes machine learning to provide a subset of semi-automated and editable measures during an echocardiography or when reviewing an already acquired echocardiography. When Auto Measure Version 2 is enabled, the healthcare professional performs an echocardiography with a workflow that provides the user with a semi-automated measurement that can be edited, accepted, or rejected.

Philips has designed Auto Measure as a “locked” algorithm prior to marketing. As defined by FDA in the discussion paper Proposed Regulatory Framework for Modifications to AI/ML Based Software as a Medical Device (SaMD) published April 2, 2019, this “locked” algorithm provides the same result each time the same input is applied to it and does not change with use.

The Auto Measure software feature does not introduce new modes, presets, measurements, or system components (e.g. transducers) to the Philips 5000 Compact Series Ultrasound Systems K222648.

No hardware changes to the 5000 Compact Series Ultrasound Systems K222648 are required when using the Auto Measure feature, and existing, commercialized Philips transducers are used for the Auto Measure feature.

5000 Compact Series Ultrasound Systems are part of the VM platform product family, The Auto Measure Version 1 feature was originally cleared (K211597) on EPIQ and Affiniti models running software version 9.0 (VM9.0). The Auto Measure feature is also available to all software releases following VM9.0.

Since the initial Auto Measure feature initial clearance (Version 1.0), a subset of integrated measurement detectors has been trained with additional training data in the Auto Measure feature (Version 2) which is scope of this submission

Auto Measure for this premarket notification utilizes the same software version platform VM as the Reference Device, Affiniti Diagnostic Ultrasound Systems K211597.

IV. Intended Use and Indications for Use

5000 Compact Series Intended Use

The intended use of 5000 Compact Ultrasound System is diagnostic ultrasound imaging and fluid flow analysis of the human body.

5000 Compact Series Indications for Use:

The 5000 Compact Series Ultrasound Systems (Ultrasound System 5500G, Ultrasound System 5500P, Ultrasound System 5500W, Ultrasound System 5500CV, Ultrasound System 5300G, Ultrasound System 5300P, Ultrasound System 5300W) are intended for diagnostic Ultrasound imaging in B (or 2D), 3D/4D, Color Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-mode (including anatomical M-mode), Harmonics (Tissue and Contrast), Color Power Angio (CPA), and Combined modes.

The intended use of the 5000 Compact series ultrasound system is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following indications for use: Abdominal, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral Vascular, Cephalic (Adult) , Cephalic (Neonatal),Fetal Echo, Fetal/Obstetric, Gynecological, Intraoperative(Vascular),Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Pediatric, Peripheral Vessel, Small Parts, Transesophageal (Cardiac), Transrectal, Transvaginal and Urology.

The clinical environments where the 5000 Compact Series Ultrasound Systems can be used include physicians' office, clinics, hospitals, surgical suites 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. However, nothing stated in the user information reduces the user's responsibility for sound clinical judgment and best clinical procedure. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed.

However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure

Note: There are no changes to the 5000 Compact Ultrasound System Indications for Use due to the introduction of the Auto Measure Version 2

Feature	5000 Compact Series Ultrasound Systems with Auto Measure Version 2	5000 Compact Series Ultrasound Systems (K 222648) Primary predicate device	Affiniti Diagnostic Ultrasound System VM9.0 (K211597) Reference Device	Comparison
	<p>physicians, and biomedical engineers who operate and maintain your product. Trained healthcare Professional</p> <p>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 5000 Compact Series Ultrasound Systems.</p>	<p>physicians, and biomedical engineers who operate and maintain your product. Trained healthcare Professional</p> <p>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 5000 Compact Series Ultrasound Systems.</p>	<p>physicians, and biomedical engineers who operate and maintain your product. Trained healthcare Professional</p> <p>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.</p>	
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.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical to Predicate
USA FDA Classification	Class II	Class II	Class II	Identical to Predicate
Primary Product Code	IYN	IYN	IYN	Identical to Predicate
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	21 CFR 892.1550	Identical to Predicate
Secondary Product Codes	ITX IYO QIH	ITX IYO	ITX IYO QIH	Identical to Predicate

Feature	5000 Compact Series Ultrasound Systems with Auto Measure Version 2	5000 Compact Series Ultrasound Systems (K 222648) Primary predicate device	Affiniti Diagnostic Ultrasound System VM9.0 (K211597) Reference Device	Comparison
Secondary Regulation Name	System, imaging, pulsed echo, ultrasonic Transducer, ultrasonic, diagnostic Automated Radiological Image Processing Software	System, imaging, pulsed echo, ultrasonic Transducer, ultrasonic, diagnostic Automated Radiological Image Processing Software	System, imaging, pulsed echo, ultrasonic Transducer, ultrasonic, diagnostic Automated Radiological Image Processing Software	Identical to Predicate
Secondary Regulation Number	21 CFR 892.1570 21 CFR 892.1560 21 CFR 892.2050	21 CFR 892.1570 21 CFR 892.1560	21 CFR 892.1570 21 CFR 892.1560 21 CFR 892.2050	Identical to Predicate
Software Platform	VM	VM	VM	Identical to Predicate
Auto Measure Software Version	2	Not available	1	Difference No.1 The detectors for a subset of measurements available with the Auto Measure feature have undergone additional training since the original release of the feature on Affiniti Series Ultrasound System VM9.0. Architecture of all detectors, training procedure and all acceptance criteria for the additional training data are identical to Auto Measure Version 1
Reusable	Yes	Yes	Yes	Identical to Predicate

Feature	5000 Compact Series Ultrasound Systems with Auto Measure Version 2	5000 Compact Series Ultrasound Systems (K 222648) Primary predicate device	Affiniti Diagnostic Ultrasound System VM9.0 (K211597) Reference Device	Comparison
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical to Predicate
Application Description	<p>Auto Measure is an optional software feature on the 5000 Compact Series Ultrasound System that provides the end user with semiautomated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG</p> <p>These measurements are routinely collected during a transthoracic ECG, per The American Society of Echo cardiology (ASE) recommendations</p> <p>2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam LVOT Diam Ao Sinus Diam</p>	<p>The healthcare professional performs 2D and Doppler measurements during a transthoracic echocardiogram by Manually positioning the calipers on the ultrasound's system waveform or image.</p> <p>2D modes include the following: IVSd LVIDd LVPWd LVIDs Asc Ao Diam LVOT Diam</p>	<p>Auto Measure is an optional software feature on the Affiniti Series Diagnostic Ultrasound System that provides the end user with semiautomated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG, per The American Society of Echo cardiology (ASE) recommendations</p> <p>2D modes include the following: IVSd LVIDd</p>	<p>Difference No.2</p> <p>Auto Measure is being included in the subject submission with 5000 Compact Series Ultrasound Systems</p>

Feature	5000 Compact Series Ultrasound Systems with Auto Measure Version 2	5000 Compact Series Ultrasound Systems (K 222648) Primary predicate device	Affiniti Diagnostic Ultrasound System VM9.0 (K211597) Reference Device	Comparison
	Ao STJ Diam RV Base, RV Mid, RV Length TV Annulus Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	Ao Sinus Diam Ao STJ Diam RV Base, RV Mid, RV Length TV Annulus Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	LVPWd LVIDs Asc Ao Diam LVOT Diam Ao Sinus Diam Ao STJ Diam RV Base, RV Mid, RV Length TV Annulus Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel	
Compatible transducers for Auto Measure	S5-1 and S4-2	S5-1 and S4-2	S5-1 and S4-2 ,x5-1, x5-1c	Identical to Predicate

Feature	5000 Compact Series Ultrasound Systems with Auto Measure Version 2	5000 Compact Series Ultrasound Systems (K 222648) Primary predicate device	Affiniti Diagnostic Ultrasound System VM9.0 (K211597) Reference Device	Comparison
Version2				
User Interface Presentation	<p>User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm.</p> <p>The user can edit, accept, or reject the measurements.</p> <p>Alternately The healthcare professional performs 2D and Doppler measurements during a transthoracic echocardiogram by Manually positioning the calipers on the ultrasound's system waveform or image.</p>	<p>The healthcare professional performs 2D and Doppler measurements during a transthoracic echocardiogram by Manually positioning the calipers on the ultrasound's system waveform or image.</p>	<p>User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm.</p> <p>The user can edit, accept, or reject the measurements.</p> <p>Alternately The healthcare professional performs 2D and Doppler measurements during a transthoracic echocardiogram by Manually positioning the calipers on the ultrasound's system waveform or image.</p>	<p>Difference No.2</p> <p>Auto Measure is being included in the subject submission with 5000 Compact Series Ultrasound Systems</p>

Comparison of subject device and secondary predicate with AI/ML capabilities

Feature	5000 Compact Series Ultrasound System Subject Devices	Affiniti Diagnostic Ultrasound System (K211597) Reference Device	Comparison
USA FDA Classification	Class II	Class II	Identical to Predicate
Primary Product Code	IYN	IYN	Identical to Predicate
Secondary Product Codes	IYO ITX *QIH	IYO ITX QIH	Identical to Predicate *QIH is new for 5000 Compact Series Ultrasound Systems
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical to Predicate
Software Version Baseline	Compact 2.0 (VM11.0)	VM9.0	Similar, 5000 Compact Series Ultrasound systems moving to VM11.0 software to gain access to Auto Measure feature.
Marketing Name of Application	Auto Measure Version 2	Auto Measure Version 1	Similar. No new measurements are introduced in Auto Measure v2. Subset of integrated measurement detectors have been trained with additional training data. CNN architecture of all detectors, training procedure and all acceptance criteria for the additional training data are identical to Auto Measure v1.
Application Description	<p>Auto Measure is an optional software feature on the 5000 Compact Series Ultrasound Systems that provides the end user with semiautomated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG, per The American Society of Echo cardiology (ASE) recommendations (Attachment 049_Literature References)</p> <p>2D modes include the following: IVSd LVIDd LVPWd</p>	<p>Auto Measure is an optional software feature on the 5000 Compact Series Ultrasound Systems that provides the end user with semiautomated adult echocardiography 2D and Doppler measurements through an AI-algorithm, training via machine-learning techniques. It is intended to be used with an Adult Cardiology Transthoracic transducer and acquisitions that include an ECG. These measurements are routinely collected during a transthoracic ECG, per The American Society of Echo cardiology (ASE) recommendations (Attachment 049_Literature References)</p> <p>2D modes include the following: IVSd LVIDd LVPWd LVIDs</p>	Identical to Predicate

Feature	5000 Compact Series Ultrasound System Subject Devices	Affiniti Diagnostic Ultrasound System (K211597) Reference Device	Comparison
	<p>LVIDs Asc Ao Diam LVOT Diam Ao Sinus Diam Ao STJ Diam RV Base, RV Mid, RV Length TV Annulus</p> <p>Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel</p>	<p>Asc Ao Diam LVOT Diam Ao Sinus Diam Ao STJ Diam RV Base, RV Mid, RV Length TV Annulus</p> <p>Doppler modes include the following: MV Peak E Vel, MV Peak A Vel MV Inflow (MV Dec Time, MV Peak E Vel, MV Peak A Vel) LVOT VTI, LVOT Vmax AV VTI, AV Vmax PV VTI, PV Vmax TR Vmax Lat E' Vel, Lat A' Vel Lat Vel (Lat E' Vel, Lat A' Vel) Med E' Vel, Med A' Vel Med Vel (Med E' Vel, Med A' Vel) RV S Vel</p>	
<p>User Interface Presentation</p>	<p>User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.</p>	<p>User selects an adult echocardiography 2D or Doppler measurement to perform then the caliper positions are initialized based on the output of the AI detection algorithm. The user can edit, accept, or reject the measurements.</p>	<p>Identical to Predicate</p>
<p>Compatible transducers</p>	<p>S5-1 and S4-2 are already commercially available and compatible with the 5000 Compact Series Ultrasound Systems. No new transducers. Transducer modes for Auto Measure: 2D, Doppler. No new transducer modes.</p>	<p>S5-1, X5-1, and S4-2 are already commercially available and compatible with the Affiniti Ultrasound System. No new transducers. Transducer modes for Auto Measure: 2D, Doppler. No new transducer modes.</p>	<p>Identical, with exemption of X5-1 transducer, which is not currently available to 5000 Compact Series Ultrasound Systems.</p>

Feature	5000 Compact Series Ultrasound System Subject Devices	Affiniti Diagnostic Ultrasound System (K211597) Reference Device	Comparison
Semi-Automation Technology	Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements. The automation of measurements is constrained to the specific imaging mode (2D, Doppler) as recommended by ASE guidelines (Attachment 049_Literature References).	Semi-automated adult echocardiography 2D and Doppler measurements are generated using an artificial intelligence (AI) detection algorithm without user interaction. After measurement is generated, the user can edit (manually adjust the caliper positions), accept, or reject the measurements. The automation of measurements is constrained to the specific imaging mode (2D, Doppler) as recommended by ASE guidelines (Attachment 049_Literature References).	Identical to Predicate

VI. Safety Considerations

The proposed 5000 Compact Series Ultrasound Systems, including the Auto Measure, 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. Performance Data

The proposed introduction of the subject Philips Auto Measure was tested in accordance with Philips internal processes.

The proposed modification of the 5000 Compact Series Diagnostic Ultrasound Systems (addition of Auto Measure) 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

Design Control activities to assure the safe and effective performance of the Auto Measure Version 2 include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications

- Design Reviews
- Software Verification

The software documentation is presented in accordance with the FDA's Guidance for Content of Premarket Submissions for Device Software Functions issued June 14, 2023.

Details of performance 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 5000 Compact Series Diagnostic Ultrasound Systems with Auto Measure. The transducer patient contact materials and manufacturing processes are not impacted by the release of the Auto Measure.

The performance of Auto Measure in 5000 Compact Series Ultrasound Systems is substantiated in Auto Measure Performance Report

Feature Performance

Automated measurements are designed to operate on transthoracic acquisitions of adult subjects with typical diagnostic image quality following known guidelines ([Guidelines for Performing a Comprehensive Transthoracic Echocardiographic Examination in Adults: Recommendations from the American Society of Echocardiography](#) or equivalent). Only trained personnel that is able to perform the selected automated measurement manually is supposed to use this feature as a workflow improvement. The operator is responsible for the final result and has to apply manual edits to the automated output whenever required. Automated measurements must not be applied to images where an appropriate manual measurement cannot be performed. As this feature has been designed to accelerate the manual measurement procedure with high success rates, no additional automated image quality assessment prevents the application of an automated measurement to inadequate images.

The Auto Measure software feature was developed to provide automated measurements in echocardiography that align closely with the accuracy of manual measurements, the current gold standard. To verify its performance, we conducted testing based on human-human interobserver data from clinical studies, which serves as a benchmark by representing the typical variation between expert clinicians. In our evaluation, Auto Measure analyzed a set of new, previously unseen echocardiography images, and its automated results were compared to ground truth measurements established by clinical experts during routine care. Both the manual and automated measurements were performed on the same images without any adjustments to the software's output or the clinical data used as ground truth. The limits of agreement (LoA) used to assess performance were derived from published human interobserver variability data. The table below presents the test results, with LoA data for each measurement detector comparing the automated outputs to the clinical ground truth, along with the acceptance criteria for each detector. All measurement detectors met the acceptance criteria informed by clinical literature, supporting the accuracy and reliability of the Auto Measure feature.

Detector performance results of Auto Measure detectors

Parameter	Detector	N (Sample Size)	Z score (A. Carkeet)	Measured Limits of Agreement (LoA) (detector prediction vs manual ground truth) "	Checked Limits of Agreement (LoAs)
Ao Sinus Diameter	DETECTOR_ID_BMODE_AO_AOSV	308	2.1320	[-11.0022%, 11.2816%]	[-35.0%, 35.0%]
Ao STJ Diameter	DETECTOR_ID_BMODE_AO_AOSTJ	301	2.1342	[-11.4181%, 13.1139%]	[-35.0%, 35.0%]
Asc Ao Diameter	DETECTOR_ID_BMODE_AO_AOASC	204	2.1769	[-14.7794%, 15.9598%]	[-35.0%, 35.0%]
IVSd	DETECTOR_ID_BMODE_LV_LVDISTANCE_SAME_LINE	305	2.1330	[-33.2114%, 28.1632%]	[-35.0%, 35.0%]
LVIDd	DETECTOR_ID_BMODE_LV_LVDISTANCE_SAME_LINE	457	2.0984	[-14.1564%, 12.4223%]	[-35.0%, 35.0%]
LVIDs	DETECTOR_ID_BMODE_LV_LVID_ES	469	2.0965	[-23.4752%, 26.0242%]	[-35.0%, 35.0%]
LVOT Diameter	DETECTOR_ID_BMODE_LV_LVOT	453	2.0991	[-17.729%, 16.1588%]	[-35.0%, 35.0%]
LVPWd	DETECTOR_ID_BMODE_LV_LVDISTANCE_SAME_LINE	305	2.1330	[-33.1364%, 29.9544%]	[-35.0%, 35.0%]
RV Base	DETECTOR_ID_BMODE_RV_RVD_BASE	302	2.1339	[-16.1373%, 25.9079%]	[-35.0%, 35.0%]
RV Mid	DETECTOR_ID_BMODE_RV_RVD_MID	243	2.1564	[-25.0913%, 30.2573%]	[-35.0%, 35.0%]
RV Length	DETECTOR_ID_BMODE_RV_RVL	117	2.2599	[-14.6089%, 13.3871%]	[-35.0%, 35.0%]
TV Annulus	DETECTOR_ID_BMODE_RV_TVANN	53	2.4511	[-19.3628%, 18.0347%]	[-35.0%, 35.0%]

MV Decel. Time	DETECTOR_ID_DOPPLER_MV_DECEL_E_DURATION	136	2.2343	[-23.5717%, 22.8591%]	[-25.0%, 25.0%]
MV Peak A Vel	DETECTOR_ID_DOPPLER_MV_VMAX_A_VELOCITY	229	2.1631	[-12.3694%, 15.2363%]	[-24.0%, 24.0%]
MV Peak E Vel	DETECTOR_ID_DOPPLER_MV_VMAX_E_VELOCITY	136	2.2343	[-9.2081%, 9.1223%]	[-24.0%, 24.0%]
AV VTI	DETECTOR_ID_DOPPLER_AV_VTI	247	2.1546	[-21.5393%, 19.8925%]	[-22.0%, 22.0%]
LVOT VTI	DETECTOR_ID_DOPPLER_LVOT_VTI	234	2.1607	[-17.267%, 17.2093%]	[-22.0%, 22.0%]
PV VTI	DETECTOR_ID_DOPPLER_PV_VTI	66	2.3864	[-20.6140%, 21.0567%]	[-22.0%, 22.0%]

Performance validation data have been extracted from a total of 500 studies, one study per subject. Of these 500 studies, 200 are known normal subjects and 300 patients (198 patients had a confirmed pathology). In clinical routine, not all measurements are performed in all studies. The available data per detector are listed in column 3 above. Demographic distribution for all validation studies is as follows:

Age	52.4 ± 15.5 years
Gender	<ul style="list-style-type: none"> • Male: 49.6 % • Female: 50.4 %
Ethnicity	<ul style="list-style-type: none"> • Asian: 30.2 % • Black: 26.4 % • White: 36.2 % • Other: 7.3 %
Body Surface Area	1.9 m ² ± 0.2 m ²
Weight	76.8 kg ± 17.0 kg

All detector models were trained from the ground up and no pre-trained model weights were used. Training of the detectors was based on manual measurements performed by human experts done for diagnostic purpose. No additional non-standard annotation was required.

Data pool for semi-automated cardiac measurement consists of anonymized transthoracic echocardiography DICOM data and metadata. The data was recorded by multiple sonographers and physicians qualified in echocardiography in a large sample of adults of various ethnicities. Echocardiographic recordings were acquired according to guideline-standard echocardiographic procedures between 2010 and 2021 in 20

centers and 16 countries. Qualified medical professionals educated in echocardiography using TTA software (versions TTA2.31.00 and TTA2.50.00) or various Philips ultrasound systems annotated the echocardiographic data following established guidelines (Mitchell et al 2019).

The total training pool comprises more than 6000 studies from the general population, cardially healthy individuals as well as from patients having indications for receiving an echocardiogram. Following our standard operating procedure for AI based algorithm development, validation data have been randomly sampled from the total pool and then separated before detector development. Remaining data have been used for training and tuning in a cross-validation framework.

VIII. Clinical Data

Clinical investigations were not required for this premarket submission of the 5000 Compact Series Diagnostic Ultrasound Systems with Auto Measure software feature

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

Results of the testing 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.

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