Philips Medical Systems
Tamara Daniels
Senior Regulatory Affairs Manager
22100 Bothell Everett Hwy
BOTHELL WA 98021

September 8, 2021

Re: K211597
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: August 10, 2021
Received: August 12, 2021

Dear Tamara Daniels:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211597

Device Name

EPIQ Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of Philips EPIQ series diagnostic ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

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

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

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

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211597

Device Name

Affiniti Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of the Affiniti Series Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use:

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

The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

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

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

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510(k) number: K211597

510(k) Summary

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

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Tamara Daniels Senior Manager, Regulatory Affairs 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Phone: 203.213.6862 Fax: 425.402.3481
Secondary Contact Information	Anne Rossi Director, Regulatory Affairs 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Phone: 425.256.0664 Fax: 425.402.3481
Date Prepared	August 10, 2021

II. Device

Proprietary Name	Philips EPIQ Series Diagnostic Ultrasound System Philips Affiniti Series Diagnostic Ultrasound System
Common Name	Auto Measure Diagnostic Ultrasound System and Transducers Automated Radiological Image Processing Software
Regulation Description	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasound transducer Picture archiving and communications system
Primary Regulation Number and Product Code	892.1550, IYN
Secondary Regulation Number and Product Codes	892.1560, IYO 892.1570, ITX 870.1200, OBJ* 892.2050, QIH

**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
Classification Panel	Radiology

III. Predicate & Reference Devices

Primary Predicate Devices:

- K202216 EPIQ Series Diagnostic Ultrasound System
- K201012 Affiniti Series Diagnostic Ultrasound System

Reference Predicate Device:

- K200974 QLAB Advanced Quantification System

IV. Device Description

Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems are durable, reusable capital equipment medical devices intended for high-resolution general imaging; interventional radiology, cardiology, vascular, obstetrics, and gynecology applications; and fluid flow analysis. They are intended to be used by trained professionals at various settings of patient care such as clinical admission, periodic evaluations, prior to hospitalization discharge, and/or academic research, via maneuverable caster wheels or mobile handheld components.

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the Auto Measure software-only feature for use on the Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems. The Philips Auto Measure feature provides the end user with semi-automated functionality for a subset of 2D and Doppler measurements currently available on the Philips EPIQ and Affiniti systems when performing or reviewing an adult transthoracic echocardiography (TTE) with simultaneously acquired electrocardiogram (ECG). The AI/ML-enabled algorithm is designed to produce semi-automated and editable measures.

The Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems were selected as the primarypredicate for the subject device. This application provides a semi-automated means to perform 2D and Doppler measurements during an echocardiography test. The end user can edit, accept, or reject the measurement(s). On the predicate devices, the end user would perform these measurements manually.

This technology is similar to the cleared QLAB feature (3D Auto MV). The Philips QLAB Advanced Quantification Software System (QLAB) is designed to view and quantify image data acquired on Philips EPIQ and Affiniti Ultrasound Systems. The 3D Auto MV feature is a cardiac quantification application with a machine learning algorithm.

V. Indications for Use

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

VI. Comparison of Technological Characteristics with Predicate Device

The selection of the predicate devices (K202216, K201012) is based on the similarity in indications for use, clinical use scenarios, and principles of operation among devices. The introduction of the Auto Measure feature does not modify the Philips EPIQ and Affiniti Ultrasound System indications.

The Auto Measure feature functionality does not introduce any new transthoracic echo measurements. With a machine learning algorithm, this feature allows the end user the enable semi-automated, editable measurements when performing an adult transthoracic echocardiogram in 2D and Doppler modes. The end user can also disable Auto Measure functionality on the 2D and Doppler measurements. The Auto Measure feature provides the same measurements as the predicate devices.

The selection of the reference device (K200974) is based on the similarity of the functionality and product code QIH (automated radiological image processing software), specifically the most recently cleared feature, 3D Auto MV. Similar to Auto Measure, 3D Auto MV uses machine learning to develop an algorithm that provides the user with semi-automated functionality for various measurements.

VII. Performance Data

The proposed introduction of the subject Philips Auto Measure feature was tested in accordance with Philips internal processes. Design Control activities to assure the safe and effective performance of the Auto Measure feature include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications
- Design Reviews
- Software Verification and Validation

Non-clinical testing also included the Performance Validation Study for the proposed Auto Measure software application.

Software Verification and Validation testing were used to support substantial equivalence of the new Auto Measure feature (as part of the EPIQ / Affiniti System software release version 9.0) to the currently marketed manual measuring options. The software documentation is presented in accordance with the FDA's *Guidance for Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005.

VIII. Conclusion

Based on adherence to the aforementioned Philips internal processes and the successful verification and validation testing, the proposed Auto Measure software feature is substantially equivalent to the predicate device Philips EPIQ and Affiniti Series Ultrasound Systems. Testing performed demonstrated that the proposed Auto Measure feature meets the defined requirements and performance claims.