Philips Ultrasound, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

September 2, 2020

Re: K202216
Trade/Device Name: EPIQ Series Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, OBJ
Dated: August 5, 2020
Received: August 6, 2020

Dear Prithul Bom:

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)*
K202216

Device Name
EPIQ Series Diagnostic Ultrasound Systems

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.

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, and only for the purposes for which it was 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.

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K202216

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.
Date Prepared: August 31, 2020

I. Submitter

Manufacturer Name and Address
Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact Information
Colin S. Jacob
Senior Regulatory Affairs Specialist
TEL: 425.908.1209
EMAIL: colin.jacob@philips.com

II. Device

Trade Name	EPIQ Series Diagnostic Ultrasound Systems
Common Name	Diagnostic ultrasound system and transducers
Regulation Description	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer Diagnostic intravascular catheter
Regulation Number	892.1550 892.1560 892.1570 870.1200
Primary Product Code	IYN
Secondary Product Codes	IYO ITX OBJ
Device Class	Class II
Classification Panel	Radiology

III. Predicate Device

- K200304 - Philips EPIQ Series Diagnostic Ultrasound Systems

IV. Device Description

Philips EPIQ Diagnostic Ultrasound Systems are durable, reusable capital equipment / medical devices which are software-controlled and intended for high-resolution general imaging, interventional radiology, cardiology, vascular and OB/GYN 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.

Software modes/applications, scanning protocols, and pre-installed settings or functionality to create dedicated settings for imaging of specific anatomy are available with the subject Philips EPIQ Diagnostic Ultrasound Systems and may vary among model configurations.

The systems are manufactured with hardware components which consist of:

1) a primary console (e.g., workstation, tablet) with built-in software components, features, and various clinical applications, and
2) a range of compatible ultrasound transducers and ultrasound intravascular catheters.

A suite of reusable compatible transducer types are offered such as transesophageal echocardiography (TEE) transducers, non-imaging (pencil) probes, curved array, linear array and sector/phased array. Philips ultrasound transducers may be bagged into compatible transducer/probe cover sheaths, designed by other manufacturers, for each procedure to prevent cross-contamination and reduce the risk of healthcare-associated infections. Philips EPIQ Diagnostic Ultrasound Systems are also compatible with single-use diagnostic intravascular ultrasound catheters (i.e., Philips VeriSight Intracardiac Echocardiography (ICE) Catheter, VeriSight Pro Intracardiac Echocardiography (ICE) Catheter) that are intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart for image guidance during cardiac interventional procedures.

Some configurations may have additional previously-cleared accessories, components and software features which are manufactured by Philips Ultrasound, Inc. or other manufacturers.

V. Indications for Use

Device	Indications for Use
Philips EPIQ 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. 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, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

VI. Comparison of Technological Characteristics between Proposed Subject Device and Predicate Device

Standard Feature	Philips EPIQ Series Diagnostic Ultrasound Systems K202216 (Subject Device)	Philips EPIQ Series Diagnostic Ultrasound Systems K200304 (Predicate Device)	Comparison
Regulation Number	892.1550	892.1550	Same
Device Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Same
Product Code	IYN	IYN	Same
Secondary Product Code	IYO, ITX, OBJ	IYO, ITX	Subject of submission
Indications for Use	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,	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 Echo), 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,	Subject of submission Indications for use of EPIQ is being updated to include “Intra-cardiac echo, Intra-luminial” to reflect compatibility with ultrasound intravascular catheters (K200812)

Standard Feature	Philips EPIQ Series Diagnostic Ultrasound Systems K202216 (Subject Device)	Philips EPIQ Series Diagnostic Ultrasound Systems K200304 (Predicate Device)	Comparison
	Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal. 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, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound	Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal. 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, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound	

Standard Feature	Philips EPIQ Series Diagnostic Ultrasound Systems K202216 (Subject Device)	Philips EPIQ Series Diagnostic Ultrasound Systems K200304 (Predicate Device)	Comparison
	clinical judgement and best clinical procedure.	clinical judgement and best clinical procedure.	
Reusable?	Yes	Yes	Same
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Same
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Same
Principles of Operation	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	Same
Type of Compatible Components	TEE Probes Non-imaging (pencil) probes Curved Array Transducers	TEE Probes Non-imaging (pencil) probes Curved Array Transducers	Subject of submission

Standard Feature	Philips EPIQ Series Diagnostic Ultrasound Systems K202216 (Subject Device)	Philips EPIQ Series Diagnostic Ultrasound Systems K200304 (Predicate Device)	Comparison
	Linear Array Transducers Sector Array Transducers Ultrasound Intravascular Catheters*	Linear Array Transducers Sector Array Transducers	
Acoustic Outputs Within Range?	Yes	Yes	Same
Previously cleared Imaging Modes?	Yes	Yes	Same

*Compatible ultrasound intravascular catheter in K200812.

VII. Performance Data

Relevant non-clinical verification testing and compatibility information has been performed and included in this submission to address system level requirements according to system and design specifications, and risk control measures. The proposed Philips EPIQ Diagnostic Ultrasound Systems did not require clinical data for determination of substantial equivalence.

The proposed Philips EPIQ Series Diagnostic Ultrasound Systems with the VeriSight ICE / PRO ICE Catheters is an electronic product as defined by 21 CFR Subject Chapter J regulations, and is Track 3 Device and complies with the referenced standard as well as the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducer*s, issued on June 27, 2019.

Philips Ultrasound, Inc. performed the following testing to ensure the safety and effectiveness of the proposed Philips EPIQ Series Diagnostic Ultrasound Systems with the VeriSight ICE / PRO ICE catheters:

- ANSI/AAMI 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012,
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014,
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015.

VIII. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject Philips EPIQ Series Diagnostic Ultrasound Systems with VeriSight ICE / PRO ICE Catheters meet their intended use. The results of the relevant performance data and compatibility support a determination that the proposed subject device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device.