May 12, 2023

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

Re: K231190
Trade/Device Name: EPIQ 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: April 26, 2023
Received: April 26, 2023

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,

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231190

Device Name

EPIQ Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of 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), 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 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.

PHILIPS

510(k) Summary #K231190

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

Date Prepared: March 24, 2023

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	Courtney Nix Senior Regulatory Affairs Specialist 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Secondary Contact	Tamara Daniels Senior Regulatory Affairs Manager 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA

II. Device

Proprietary Name	EPIQ Series Diagnostic Ultrasound System
Common Name	Diagnostic Ultrasound System and Transducers
Product Code; Regulation Description; Regulation Number	IYN; Ultrasonic Pulsed Doppler Imaging System; 21 CFR 892.1550 (Primary) IYO; Ultrasonic Pulsed Echo Imaging System; 21 CFR 892.1560 ITX; Diagnostic Ultrasonic Transducer; 21 CFR 892.1570 OBJ; Diagnostic Intravascular Catheter; 21 CFR 870.1200 QIH; Medical Image Management and Processing System; 21 CFR 892.2050
Device Class	Class II
Review Panel	Radiology
Predicate Device	K212704; Philips EPIQ Series Diagnostic Ultrasound System
Reference Device	K162329; CX50 Diagnostic Ultrasound System, Sparq Diagnostic Ultrasound System

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the mL26-8 transducer:

The mL26-8 is a linear array transducer designed primarily for superficial high-resolution imaging in Musculoskeletal (Superficial), Ophthalmic, Pediatric, Peripheral Vessel, and Small Organ (Breast, Thyroid, Testicle). The mL26-8 has a frequency of 6-13.33 MHz.

IV. 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.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the mL26-8 transducer to the EPIQ Series Diagnostic Ultrasound Systems.

The intended users, use environment, intended use, accessories and offered features are unchanged as compared to the predicate. The expansion of the indications for use to include Ophthalmic is supported by the reference device. All other indications are unchanged from the predicate device.

VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System, including mL26-8, 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. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed EPIQ Series Diagnostic Ultrasound System:

- ANSI/AAMI ES 60601-1: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance, 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text)
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
- IEC 60601-1-6 Medical Electrical Equipment Part 1-6, General Requirements for Basic Safety and Essential Performance- Collateral standard: Usability, 2013
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62304: Medical Device Software – Software life cycle process, 2015
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017-09
- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; 2018

Non-Clinical performance testing has been conducted addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of EPIQ Series Diagnostic Ultrasound System include but are not limited to the following:

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

VIII. Clinical Data

The proposed EPIQ Series Diagnostic Ultrasound System did not require clinical data for determination of substantial equivalence since substantial equivalence was demonstrated based on the following attributes:

- Design features
- Indications for use
- Fundamental scientific technology
- Non-clinical performance testing
- Safety and effectiveness

IX. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed EPIQ Series Diagnostic Ultrasound System, including mL26-8, met the intended use.

While the predicate, Philips EPIQ Diagnostic Ultrasound System (K212704), does not have the 'Ophthalmic' indication, the L12-4 transducer, currently compatible with and cleared on the reference device, CX50 Diagnostic Ultrasound System, Sparq Diagnostic Ultrasound System (K162329), is currently indicated for 'Ophthalmic'. Furthermore, the proposed mL26-8 has a higher frequency when compared to the existing compatible transducer on the Philips EPIQ Diagnostic Ultrasound System, however, the proposed mL26-8 transducer's frequency is within the limits of the Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued in February 2023. The additional indication and higher frequency enhances the predicate device, the Philips EPIQ Diagnostic Ultrasound System (K212704), these design changes do not significantly affect the use of the device, nor do they introduce any new or significantly modified risks. The differences between the proposed device and the predicate and reference devices do not raise new questions of safety and/or effectiveness. Therefore, the proposed EPIQ Series Diagnostic Ultrasound System is similar to the predicate, Philips EPIQ Diagnostic Ultrasound System, in terms of indications for use, design, technological characteristics, modes of operations, safety and effectiveness.