



November 30, 2023

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

Re: K233545

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: November 3, 2023  
Received: November 3, 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 (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](mailto: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

## Indications for Use

510(k) Number (if known)  
K233545

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.

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

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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:                     K233545                    

Date Prepared: August 30, 2023

### I. Submitter

|                                      |  |
|--------------------------------------|--|
| <b>Manufacturer Name and Address</b> | Philips Ultrasound LLC<br>22100 Bothell Everett Hwy<br>Bothell, WA 98021-8431 USA                                |
| <b>Contact Information</b>           | Mike Chambers<br>Senior Regulatory Affairs Specialist<br>22100 Bothell Everett Hwy<br>Bothell, WA 98021-8431 USA |
| <b>Secondary Contact</b>             | Tamara Daniels<br>Senior Regulatory Affairs Manager<br>22100 Bothell Everett Hwy<br>Bothell, WA 98021-8431 USA   |

### II. Device

|  |  |
|--|--|
| <b>Proprietary Name</b>  | EPIQ Series Diagnostic Ultrasound System   |
| <b>Common Name</b>   | Diagnostic Ultrasound System and Transducers   |
| <b>Product Code;<br/>Regulation Description;<br/>Regulation Number</b> | <b>Primary</b><br>IYN; Ultrasonic Pulsed Doppler Imaging System; 21 CFR 892.1550<br><br><b>Secondary</b><br>IYO; Ultrasonic Pulsed Echo Imaging System; 21 CFR 892.1560<br>ITX; Diagnostic Ultrasonic Transducer; 21 CFR 892.1570<br>OBJ; Diagnostic Intravascular Catheter; 21 CFR 870.1200<br>QIH; Medical Image Management and Processing System; 21 CFR 892.2050 |
| <b>Device Class</b>  | Class II   |
| <b>Review Panel</b>  | Radiology  |
| <b>Predicate Device</b>  | K231190; Philips EPIQ Series Diagnostic Ultrasound System  |

### III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the X11-4t transducer:

The X11-4t is a 2500 element phased array 3D (three dimensional) transesophageal (TEE) cardiac transducer for patients 5 kg and greater. This transducer is supported by all EPIQ platform systems running software version 11.0 or higher including the EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, and EPIQ 5. X11-4t supports Cardiac Adult, Cardiac Pediatric, and Transesophageal

(Cardiac) indications. The X11-4t has a frequency of 4-11 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 X11-4t 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.

#### VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System, including X11-4t, 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 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 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 X11-4t, met the intended use.

The proposed Philips EPIQ Diagnostic Ultrasound System has identical indications to the predicate Philips EPIQ Diagnostic Ultrasound System (K231190). All comparison points between the subject X11-4t transducer and the S7-3t and X8-2t TEE transducers (compatible with the predicate EPIQ Diagnostic Ultrasound System) are either identical or equivalent. The differences between the proposed device and the predicate device 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.