May 27, 2026

Philips Ultrasound, LLC
Aditi Chaubal
Senior RA Manager
22100 Bothell Everett Hwy
Bothell, Washington 98021

Re: K260123
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 24, 2026
Received: April 27, 2026

Dear Aditi Chaubal:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260123

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, 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.

• Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

• 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(k)

Philips Ultrasound

EPIQ Series Diagnostic Ultrasound System

510(k) Summary

Section 10.02 510(k) Summary

510(k) Number: K260123

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

1. Submitter's name, address, telephone number, contact person(s)

Manufacturer: Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact Person: Aditi Chaubal
Senior RA Manager
aditi.chaubal@philips.com
1-425-482-8243

Secondary Contact: Irma Sandoval-Watt
Senior RA Manager
Irma.Sandoval-Watt@philips.com
1-303-453-3421

Date Prepared: May 26, 2026

2. Name of the device, including the trade of proprietary name if applicable, the common or usual name, and the classification name, if known:

Proprietary Name: EPIQ Series Diagnostic Ultrasound System

Common Name: Diagnostic ultrasound system and transducers

Regulation Description:

Classification Name	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
Catheter, ultrasound, intravascular	870.1200	OBJ

Device Class: Class II

Classification Panel: Radiology

3. Device Description Summary

The Philips EPIQ Series Diagnostic Ultrasound Systems are general purpose, software controlled, diagnostic ultrasound systems. Their function is to acquire ultrasound data and to display the data in various modes of operation. The systems consist of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics, and the transducer connection points. In addition to the physical knobs and buttons of the main control panel, the user interface consists of a touch screen with soft key controls. The transducers connect to the system console and facilitate ultrasound scanning of patients.

There are multiple marketing-named versions of the EPIQ Series Diagnostic Ultrasound systems. Each version of the EPIQ systems can have multiple feature configurations that are based on different software feature options and hardware options.
This submission introduces the eV14-2v transducer on the Philips EPIQ Series Diagnostic Ultrasound Systems.

eV14-2v Transducer

The eV14-2v is a broadband, endocavitary PureWave transducer with elevation focus. It is 3D/4D capable and features multi-row array technology. It is designed to support obstetric and gynecological applications. The transducer offers a variety of imaging modes, including 2D, PW Doppler, Color Flow, M-mode, 3D/4D, and Elastography.
eV14-2v includes a curved linear array with 6 MHz center frequency and 10.5 mm azimuth radius of curvature. The array has a total of 436 elements arranged in 3 rows of 218 elements. The inner row of 218 elements provide an "inner" elevation aperture 3 mm in height. This row is connected to 128 system channels via a high-voltage multiplexer. The two outer rows of 218 elements are electrically connected together and, also via a high-voltage multiplexer, can be selectively connected to the same 128 system channels, resulting in the "full" aperture height of 6 mm. The ability to switch between inner and full apertures provides the means to achieve both low clutter in the near field and penetration in the far field. The same multiplexer provides the ability to translate these apertures in the azimuth direction provides the field of view. The multiplexer is controlled by data signals provided by the system to coordinate azimuth aperture position with the system beamformer. The linear curved array can be mechanically rotated and acquire planar tomographic slices for reconstructing 3D/4D images.
The eV14-2v consists of a linear curved array, rotational mechanism and drive train, motor, and interconnect circuitry. A transducer housing assembly encloses the lens module assembly (LMA) and an integral connectorized cable assembly provides interface to the system. The connectorized cable assembly contains a cable and a connector with PCBs providing cable and system interconnect, electrical tuning, multiplexer control, and system interface features.

4. Intended Use and Indications for Use

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, 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.

- Modes of operation include: B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

- 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.

Indications for Use for eV14-2v Transducer:

The indications for use for the eV14-2v transducer are Fetal/OB, Other: Fetal Echo, Other: GYN, Other: Urology, and Transvaginal.

5. Substantially Equivalent Devices

- **Predicate Device (Transducer)**: 3D9-3V with EPIQ Series Diagnostic Ultrasound System (K160807)
- **Reference Device 1 (Transducer):** V9-2 with EPIQ Series Diagnostic Ultrasound System (K182857)
- **Reference Device 2 (Transducer):** C9-4ec with Lumify Diagnostic Ultrasound System (K242519)

6. Technological Comparison to Predicate & Reference Devices

Feature/ Characteristic	EPIQ Series Diagnostic Ultrasound System with eV14-2v Transducer Subject	EPIQ Series Diagnostic Ultrasound System with 3D9-3V Transducer (K160807) Predicate	Comparison/ Discussion/ Comments
System level Feature/Characteristics			
Regulation Number	892.155	892.155	Identical
Device Classification Name	II	II	Identical
Primary Product Code	IYN	IYN	Identical
Secondary Product Codes	IYO, ITX, OBJ, QIH	IYO, ITX, OBJ, QIH	Identical
Intended Use	Intended for diagnostic ultrasound imaging and fluid flow analysis	Intended for diagnostic ultrasound imaging and fluid flow analysis	Identical
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.	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.	Identical
Modes of Operation	B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, Harmonic Imaging	B Mode (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, Harmonic Imaging	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Users	Trained healthcare professionals	Trained healthcare professionals	Identical

Feature/ Characteristic	EPIQ Series Diagnostic Ultrasound System with eV14-2v Transducer Subject	EPIQ Series Diagnostic Ultrasound System with 3D9-3V Transducer (K160807) Predicate	Comparison/ Discussion/ Comments
Use Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical
Transducer Features	**eV14-2v**	**3D9-3V**	
Transducer Model	Endocavitary Curved Linear Transducer	Endocavitary Curved Linear Transducer	Identical
Indications for Use	Fetal/OB; Fetal Echo; Trans-vaginal; GYN; Urology	Fetal/OB; Fetal Echo; Trans-vaginal; GYN; Urology	Identical
Acoustic Output	Ispta.3 ≤ 720 (mW/cm2) TI ≤ 6.0 MI ≤ 1.9	Ispta.3 ≤ 720 (mW/cm2) TI ≤ 6.0 MI ≤ 1.9	Identical
Acoustic Working Frequency	Center Frequency 6.1MHz	Center Frequency 5.7 MHz	Similar
Geometrical Configuration	Curved Linear Array	Curved Linear Array	Identical
Total Number of elements	436 addressable elements connected to form dual aperture array with 218 elements per aperture	128	Different
Field of View (Degrees)	180 degrees	155.5 degrees	Different
Transducer Modes of Operation	B (2D); M-mode; PW; Doppler; 3D/4D, Color; MPR	B, M, PWD, Color; 3D/4D; Doppler, Combined	Similar
Tip Dimensions	Height: 25.3mm Width: 25.3mm Tip Diameter: 25.3 mm	Height: 26.3mm Width:26.3mm Tip Diameter: 26.3 mm	Different
Connector	Cart-based system transducer connector	Cart-based system transducer connector	Identical
Weight (Including connector and cable)	< 0.9 kg (including connector and cable)	< 1.2 kg (including connector and cable)	Similar
Radiated Field Operating Controls	The transducer is controlled via the Ultrasound System's control panel.	The transducer is controlled via the Ultrasound System's control panel.	Identical
Patient Contact Materials	Biocompatible ISO 10993-1	Biocompatible ISO 10993-1	Identical

Feature/ Characteristic	EPIQ Series Diagnostic Ultrasound System with eV14-2v Transducer Subject	EPIQ Series Diagnostic Ultrasound System with 3D9-3V Transducer (K160807) Predicate	Comparison/ Discussion/ Comments
Transducer Maximum Surface Temperature (per IEC 60601-2-37, clause 201.11)	Temperatures in °C Still Air: 42.6 Simulated Use: 42.5	Temperatures in °C Still Air: 41.8 Simulated Use: 42.5	Similar
Transducer Element Check Incorporated	Yes	Yes	Identical
Transducer Provided Sterile	No	No	Identical
Transducer Recommended use of covers	Yes	Yes	Identical
Transducer reusable	Yes	Yes	Identical
Maximum Insertion Portion Width	25.3 mm	27.3mm	Similar
Working Length (Intended Insertion Length)	150mm	165mm	Similar

7. Safety Considerations

The proposed eV14-2v transducer with EPIQ Series Diagnostic Ultrasound System are categorized as Track 3 devices.

8. Non-Clinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed product:

- IEC 62304 Medical device software - Software life cycle processes, 2006 + A 2015
- IEC62366-1 Medical devices – Part 1: Application of usability engineering to medical devices, 2015+ AMD1: 2020
- ISO 14971 Medical devices- Application of risk management to medical devices, 2019
- IEC 60601-1 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-37- Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-1-2 4.1 ed - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests; 2020
- 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 the system level requirements with the transducer according to the system and design specifications and risk control measures. The activities to assure safe and effective performance of the EPIQ Series Diagnostic Ultrasound System include but are not limited to the following:

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

9. Clinical Performance Data

The proposed EPIQ Series Diagnostic Ultrasound System with eV14-2v transducer did not require clinical data for determination of substantial equivalence since it demonstrated substantial equivalence based on the following attributes:

- Design Features
- Indications for Use
- Fundamental scientific technology
- Non-clinical performance testing
- Safety and Effectiveness

10. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed transducer eV14-2v for EPIQ Series Diagnostic Ultrasound System, does not affect the use of the device, nor does it introduce any new or significantly modified risks.
There is no change in the indications to EPIQ Series Diagnostic Ultrasound System. All comparison points between the subject eV14-2v transducer and the predicate, 3D9-3v transducer (compatible with the predicate EPIQ Series Diagnostic Ultrasound System) and reference devices (V9-2 with EPIQ Series Diagnostic Ultrasound System; C9-4ec with Lumify 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 with eV14-2v transducer is substantially equivalent to the predicate device in terms of indications for use, design, technological characteristics, modes of operations, safety and effectiveness.