October 9, 2025

Philips Ultrasound LLC
Swetha Paritala
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K251651
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: May 29, 2025
Received: September 11, 2025

Dear Swetha Paritala:

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.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251651 ?

Please provide the device trade name(s). ?

EPIQ Series Diagnostic Ultrasound System;
Affiniti Series Diagnostic Ultrasound System

Please provide your Indications for Use below. ?

EPIQ:

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.

Modes of operation include: B Mode, 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.

Affiniti:

The intended use of 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.

Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

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 judgement and best clinical procedure.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

PHILIPS

510(k) Summary

#K251651 □□□□□□□□□□□□□□□□

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

Date Prepared: January 10, 2025

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	SwethaRao Paritala Senior Regulatory Affairs Specialist 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA Swetharao.partitala@philips.com 1-412-969-1010
Secondary Contact	Priscilla Herpai Senior Regulatory Affairs Manager 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA Priscilla.Herpai@philips.com 1-610-533-7984

II. Device

Proprietary Name	EPIQ Series Diagnostic Ultrasound System Affiniti 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	K250177; EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System

III. Device Description

The purpose of this special 510(k) Pre-Market Notification is to introduce EPIQ and Affiniti Series Diagnostic Ultrasound Systems with Custom Electromagnetic Interference (EMI) filter. The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound Systems with new Custom EMI filter spare part, will reduce the electrical interferences induced by the external environments and feed the clean electrical signals to the ultrasound device, equivalent to predicate device, K250177.

Ultrasound systems are very sensitive in nature. These electrical interference couplings result in Image distortions or artifacts in Images, using this Custom EMI filter will reduce such artifact effects appearing on Ultrasound systems.

IV. Indications for Use

EPIQ:
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, 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.

Affiniti:
The intended use of 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.

Modes of operation include: B Mode, M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

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 judgement and best clinical procedure.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the EPIQ and Affiniti Series Diagnostic Ultrasound Systems with EMI Filter (optional spare part). The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems are all Track 3 Devices and comply with the referenced standards as well as the FDA Ultrasound Guidance Document, Guidance for Industrly and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued in February 2023. The subject devices are substantially equivalent to the predicate devices (K250177).

Feature	EPIQ and Affiniti Series Diagnostic Ultrasound System EMI filter Proposed Device	EPIQ and Affiniti Series Diagnostic Ultrasound System (K250177) Predicate Device	Comparison
Indications for Use	EPIQ: 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. Affiniti: 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.	EPIQ: 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. Affiniti: 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.	EPIQ: Identical to predicate device. Affiniti: Identical to predicate device.
Intended Users	Trained healthcare professionals	Trained healthcare professionals	Identical

	Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the Affiniti Series Diagnostic Ultrasound System.	Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the EPIQ Series Diagnostic Ultrasound System. Before use of the system and user information, the user must be familiar with ultrasound techniques. Sonography training and clinical procedures are not included in the User Manual or with the Affiniti Series Diagnostic Ultrasound System.	
Intended User Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical
USA FDA Classification	Class II	Class II	Identical
Primary Product Code	IYN	IYN	Identical
Primary Regulation Number	21 CFR 892.1550	21 CFR 892.1550	Identical
Secondary Product Codes	ITX IYO OBJ* QIH *Applicable only to Philips EPIQ Series Diagnostic Ultrasound System, per clearance under K202216; Not applicable for Philips Affiniti Series Diagnostic Ultrasound System	ITX IYO OBJ* QIH *Applicable only to Philips EPIQ Series Diagnostic Ultrasound System, per clearance under K202216; Not applicable for Philips Affiniti Series Diagnostic Ultrasound System	Identical. The EMI filter is not associated with product code QIH.

Secondary Regulation Name	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Diagnostic ultrasonic transducer Ultrasonic pulsed echo imaging system Diagnostic intravascular catheter Automated Radiological Image Processing Software	Identical
Secondary Regulation Number	21 CFR 892.1560 21 CFR 892.1570 21 CFR 892.2050 21 CFR 870.1200	21 CFR 892.1560 21 CFR 892.1570 21 CFR 892.2050 21 CFR 870.1200	Identical
Reusable	Yes	Yes	Identical
Duration of use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Marketing Name of Application	Custom EMI Filter Module	-	Introduction of the optional spare part Custom EMI Filter Module
Image Artifacts	Image appears clean without any Image artifacts potentially caused by the external hospital environments such as bad non isolated grounding.	Visible imperfections or distortions in an Ultrasound image that are a result of external interference. These artifacts can be caused by external factors such as conductive noise induced by the electrical powerline or poor electrical grounding can affect the overall quality of the image.	The proposed device has better & cleaner Image over Predicate Device when image artifacts may arise due to external hospital environmental factors, such as poor or non-isolated grounding. Verification and Validation Testing has been conducted with Custom EMI Filter on the EPIQ & Affiniti Systems to support Clear Image without any Image artifacts.
User Interface	Yes	Yes	Custom EMI filter doesn't involve the user interface of the system
Software Performance	Yes	Yes	Custom EMI filter doesn't involve the

			software of the system. Its primary purpose is to filter electrical powerline noise or poor electrical grounding from the hospital's end, ensuring a clean electrical source for the EPIQ/Affiniti Ultrasound systems.

VI. Safety Considerations

The subject device 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 on February 2023.

VII. Non-Clinical Performance Data

The proposed modification to the EPIQ and Affiniti Series Diagnostic Ultrasound Systems includes the integration of a Custom EMI Filter to reduce electromagnetic interference from external sources. Non-clinical testing was conducted to evaluate the impact of this modification on device performance and safety.

Nonclinical Testing Summary (21 CFR 807.92(b)(1))
Purpose of Testing:
To evaluate the impact of the EMI filter on the system's safety, performance, and electromagnetic compatibility (EMC), ensuring continued compliance with applicable standards and substantial equivalence to the predicate device.
Standards Applied:ss

- **IEC 60601-1-2:2014 + AMD1:2020** – General EMC requirements for medical electrical equipment.
- **IEC 60601-2-37:2007 + AMD1:2015** – Particular requirements for ultrasonic diagnostic equipment.

Tests Conducted:

Test Type	Description	Outcome
Radiated Emissions	Evaluated emissions from the device	Passed
Conducted Emissions	Assessed conducted noise on power lines	Passed
Electrostatic Discharge (ESD)	Tested immunity to static electricity	Passed
Radiated RF Immunity	Assessed resistance to RF fields (420–470 MHz)	Passed
Voltage Interruptions	Simulated power fluctuations	Passed
Proximity Field Testing	Evaluated performance near RF sources	Passed

Results Summary:

- All EMC tests were successfully passed.

The nonclinical testing confirms that the integration of the Custom EMI Filter does not adversely affect the safety or effectiveness of the device. The system continues to meet performance

requirements and complies with applicable EMC standards. These results support the claim of substantial equivalence to the predicate device.

VIII. Clinical Data

The proposed EPIQ and Affiniti 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 and Affiniti Series Diagnostic Ultrasound System with Custom EMI filter meets the intended use. The proposed devices and predicate device:

- Are indicated for diagnostic ultrasonic imaging.
- Have identical intended users and use environments.
- Have the same device classification, product codes.
- Have identical software.
- Are introducing no new transducers.

The differences between the proposed device and predicate device do not raise new questions of safety and/or effectiveness. The major differences include:

The Custom EMI Filter Module reduces electromagnetic interference (EMI) from external sources, providing cleaner power to the EPIQ and Affiniti Series Diagnostic Ultrasound Systems. By filtering out noise from hospital power supplies, it helps prevent image distortions and artifacts in EPIQ and Affiniti Series Diagnostic Ultrasound Systems.

Therefore, the proposed EPIQ and Affiniti Series Diagnostic Ultrasound System with Custom EMI filter is substantially equivalent or enhanced to the predicate EPIQ and Affiniti Series Diagnostic Ultrasound Systems in terms of safety and effectiveness.