Philips Ultrasound LLC
Chloé Hills
Senior Regulatory Affairs Specialist
Contact Address

May 27, 2026

Re: K260680
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, QIH, OBJ, POK
Dated: [NOTE: Use date of most recent supplement]
Received: March 1, 2026

Dear Chloé Hills :

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.05.27 08:40:45 -04'00' For

Yanna Kang, Ph.D.
Assistant Director
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

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260680

Device Name
EPIQ Series Diagnostic Ultrasound Systems
Affiniti Series Diagnostic Ultrasound Systems

Indications for Use *(Describe)*
EPIQ Series Diagnostic Ultrasound System:

The intended use of EPIQ Series Diagnostic Ultrasound 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 (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 judgment and best clinical procedure.

Affiniti Series Diagnostic Ultrasound System:

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 (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

The clinical environments where the Affiniti Series 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 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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PHILIPS

K260680

Special 510(k) Summary

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

510(k) Number: K260680

Date Prepared: April 24, 2026

I. Submitter

Manufacturer Name and Address

Philips Ultrasound LLC
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II. Device

Proprietary Name

EPIQ Series Diagnostic Ultrasound System
Affiniti Series Diagnostic Ultrasound System

Common Name

Diagnostic Ultrasound System and Transducers

Regulation Description

Classification Description	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
Diagnostic Intravascular Catheter	870.1200	OBJ*
Radiological computer-assisted diagnostic software for lesions suspicious for cancer	892.2060	POK

EPIQ only

Device Class

Class II

Review Panel

Radiology

Predicate Device

K243794 – Philips EPIQ Series Diagnostic Ultrasound System; Philips Affiniti Series Diagnostic Ultrasound System

Reference Device

K242130 - Koios Decision Support (DS)

III. Device Description

The purpose of this Special 510(k) Notification is to integrate the Koios Decision Support (DS), an artificial intelligence (AI)/machine learning (ML)-based computer-aided diagnosis (CADx) software application into the EPIQ and Affiniti Series Diagnostic Ultrasound Systems (VM14.0 software). Koios DS was cleared under K242130. Koios DS version 3.7.1 is integrated into the Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems.

Koios DS is an artificial intelligence (AI)/machine learning (ML)-enabled computer aided diagnosis (CADx) software application intended for use as an adjunct to diagnostic ultrasound examination of lesions or nodules suspicious for breast or thyroid cancer. When an image of a breast or thyroid lesion is acquired on an ultrasound system, and sent over to the Koios DS workstation, the Koios application will process the image and respond by providing a result box with a diagnosis of the highlighted lesion. The results from the diagnosis can be displayed on the ultrasound system.

No hardware changes were made to the Epiq Series Diagnostic Ultrasound System or Affiniti Series Diagnostic Ultrasound System with the integration of the Koios DS software, and no changes were made to the existing, cleared Philips transducers used with these software applications.

The Koios DS software is supported by all EPIQ and Affiniti Series Diagnostic Ultrasound System models running software version 14.0 or higher including EPIQ CVx/CVxi, EPIQ Elite Advanced, EPIQ Elite, EPIQ 7, EPIQ 5, Affiniti CVx, Affiniti 70, Affiniti 50, and Affiniti 30.

Note: There are no changes to the EPIQ and Affiniti Series Diagnostic Ultrasound Systems' Indications for Use with the integration of the Koios DS software.

IV. Intended Use and Indications for Use

There is no change to the intended use of the subject devices, EPIQ and Affiniti Series Diagnostic Ultrasound Systems, compared to the predicate devices, EPIQ and Affiniti Series Diagnostic Ultrasound Systems (K243794), with the integration of this optional Koios DS software feature.

EPIQ Series Diagnostic Ultrasound System

Intended Use:
The intended use of EPIQ Series Diagnostic Ultrasound System is diagnostic ultrasound imaging and fluid flow analysis of the human body.

Indications for Use:

The intended use of EPIQ Series Diagnostic Ultrasound 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 (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.

Affiniti Series Diagnostic Ultrasound System

Intended Use:

The intended use of Affiniti Series Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body.

Indications for Use:

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 (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, and Harmonic Imaging.

The clinical environments where the Affiniti Series 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 this Special 510(k) Notification is to integrate the Koios Decision Support (DS), an artificial intelligence (AI)/machine learning (ML)-based computer-aided diagnosis (CADx) software application into the EPIQ and Affiniti Series Diagnostic Ultrasound Systems (VM14.0 software).

The subject device and predicate device:

- Are indicated for the diagnostic ultrasonic imaging and fluid flow analysis,
- Have identical intended users and use environments,
- Have the same device classification, product codes,
- Have identical software architecture,
- Have identical hardware, transducers, and imaging modes.

The differences between the proposed device, the predicate device, and the reference device do not present new or different questions of safety and/or effectiveness, as all devices listed herein (proposed, predicate, and reference devices) are subject to the same special controls to demonstrate safety and effectiveness. Therefore, the proposed device, with integration of the Koios DS feature, is equivalent to the predicate in terms of safety and effectiveness.

VI. Safety Considerations

The proposed EPIQ and Affiniti Series Diagnostic Ultrasound Systems, with Koios DS software integrated, and compatible transducers are all Track 3 Devices and comply with 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

The proposed modification of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems were tested in accordance with Philips internal procedures. The FDA Ultrasound Guidance Document - *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Guidance for Industry and Food and Drug Administration Staff, February 21, 2023*, was also applied.

Philips Ultrasound LLC performed the following testing to ensure the safety and effectiveness of the devices in scope of this submission, EPIQ and Affiniti Series Diagnostic Ultrasound Systems with the Koios DS software feature integrated:

- IEC 62304:2006+AMD1:2015 Medical Device Software – Software life cycle process
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices Edition 1.1 2020-06

Non-Clinical verification testing was conducted to address the change and performance test data were provided to support the modification of the integration of Koios DS to EPIQ and Affiniti Series Diagnostic Ultrasound Systems. These activities include, including but are not limited to, the following:

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

Since this is software integration only, and no new hardware was added, no acoustic output, cleaning and disinfectants, thermal, electrical, electromagnetic, and mechanical safety testing were required. Biocompatibility testing is not needed for the subject EPIQ and Affiniti Series Diagnostic Ultrasound Systems with Koios DS integration. The transducer patient contact materials and manufacturing processes are not impacted by the release of the subject EPIQ and Affiniti Series Diagnostic Ultrasound Systems with Koios DS integration.

Successful verification and validation testing of the Koios functionality (including supported transducers), which included gating logic, workflow execution, server communication, analysis lifecycle, error handling, localization, certificate validation, backup/restore, and findings management served to verify the successful software integration according to VM14.0's defined requirements and specifications. The results of these tests demonstrate that the Koios DS software feature has been successfully integrated onto the EPIQ and Affiniti Diagnostic Ultrasound Systems and functions as intended through verification.

Additionally, the successful completion of these activities contributes to the determination that there are no new or significantly modified risks of the subject device when compared to the predicate.

VIII. Clinical Data

There was no clinical investigation needed for this premarket submission of the EPIQ and Affiniti Series Diagnostic Ultrasound Systems with Koios DS software, with substantial equivalence being demonstrated based on the following attributes:

- Are indicated for the diagnostic ultrasonic imaging and fluid flow analysis,
- Have identical intended users and use environments,
- Have the same device classification, product codes,
- Have identical software architecture,
- Have identical hardware, transducers, and imaging modes.

IX. Sterilization

Not applicable: The EPIQ and Affiniti Series Diagnostic Ultrasound Systems and compatible transducers are not supplied sterile.

X. Conclusion

The subject device, EPIQ and Affiniti Series Diagnostic Ultrasound Systems with the Koios DS software feature integrated, has predicate devices which are legally marketed. Both subject device and predicate devices have the same intended use. The differences between the subject device and the predicate devices do not raise new or different questions of safety and effectiveness.

Both the subject device and the predicates were tested with the same types of non-clinical testing methods and follow the same set of standards.

Therefore, the subject device EPIQ and Affiniti Series Diagnostic Ultrasound Systems with the Koios DS software feature integrated is substantially equivalent to the predicate devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.