Philips Ultrasound, LLC
Lakshmi Sanjana Gondesi
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021

March 27, 2026

Re: K253595
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: February 25, 2026
Received: February 26, 2026

Dear Lakshmi Sanjana Gondesi:

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.03.27 08:20:54 -04'00'

For

Yanna Kang
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.	K253595	?

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 Series Diagnostic Ultrasound System

The intended use of EPIQ Ultrasound Diagnostic Series 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

The intended use of Affiniti 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), 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 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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

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510(k) Summary

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

510(k) Number : K253595

Date Prepared: March 25, 2026

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Person (Primary):	Lakshmi Sanjana Gondesi Senior Regulatory Affairs Specialist Philips Ultrasound LLC 22100 Bothell Everett Highway Bothell, WA 98021 sanjana.gondesi@philips.com Phone: 1 425-482-8200
Contact Person (Secondary):	Irma Sandoval-Watt Senior Regulatory Manager Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA irma.sandoval-watt@philips.com Phone: 1-303-453-3421

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*

Device Class	Class II
Review Panel	Radiology
Predicate Device	K243794, EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound (Philips Ultrasound LLC)
Reference Device	K231966, LOGIQ E10 (GE Medical Systems Ultrasound and Primary care Diagnostics, LLC)

**OBJ product code applicable only to Philips EPIQ Series Diagnostic Ultrasound System*

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the addition of the Artificial Intelligence (AI) Auto Measure Abdomen feature software application onto the EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound Systems.

The Auto Measure Abdomen feature on Philips EPIQ and Affiniti Series Diagnostic Ultrasound System aims to improve workflow efficiency by automating selected measurements required for routine abdominal and renal exams. The Auto Measure feature is designed to provide semi-automated and editable measures of abdominal organs such as kidney and spleen. The software provides a semi-automated measurement capability. Users may adjust the position of the caliper end points for measurement refinement or perform additional manual measurements. The Auto Measure Abdomen feature is available in C5-1 and C9-2 transducers only.

The software applications are supported by all EPIQ and Affiniti models running software version 14.0 or higher.

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IV. Intended Use and Indications for Use

EPIQ Intended 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 Indications of 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 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.

Note: There are no changes to the Affiniti Ultrasound System Indications for Use due to addition of the Auto Measure Abdomen feature. This software feature is associated with the Abdomen Adult indication supported on transducers C5-1 and C9-2 only that was cleared through K132304.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce Auto Measure Abdomen feature software application to the EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System. The proposed device is substantially equivalent to the predicate device (K243794).

The proposed devices 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 and product codes.
- Have identical software architecture.
- Have identical hardware and imaging modes.

The major difference between proposed device and predicate is Auto Measure feature used in predicate device (K243794) is used for cardiac indication. The proposed device Auto Measure Abdomen feature will be available under previously cleared abdominal indication (K132304) for EPIQ and Affiniti Series Diagnostic Ultrasound Systems. Performance study for validation was conducted for Auto Measure Abdomen that includes patients scanned by both C5-1 and C9-2.

VI. Safety Considerations

The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System, including Auto Measure Abdomen feature software application, and compatible transducers 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

The proposed modification of the EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound was tested in accordance with Philips internal procedures. Philips Ultrasound tested the proposed device per the following standards to ensure continued safe and effective

performance:

- IEC 62304 Medical device software – Software life cycle processes, 2006 + A 2015
- ISO 14971 Medical devices- Application of risk management to medical devices, 2019

Non-clinical verification testing was conducted to address the change and performance test data were provided to support the introduction of the proposed Auto Measure Abdomen software application. The activities to ensure the safe and effective performance of the software revision included, but are not limited to the following:

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

Non-clinical testing also included the Performance Validation Study for the proposed Auto Measure Abdomen software applications. A data analysis study was conducted to evaluate the performance of the AI Auto Measure Abdomen feature, where ultrasound images previously collected from 150 subjects were used to obtain AI Auto Measure Abdomen algorithm-generated measurements which were then compared to manual measurements performed by 3 clinical experts, with the manual measurements used as ground truth for the study. The clinical experts also reviewed the AI algorithm-generated measurements to either accept or edit the measurements. Images that contributed to the study were obtained from subjects who represented a broad range of demographics, body habitus, and the range of measurements that were representative of the intended population.

AI Testing Summary

Auto Measure Abdomen:

a. Summary of test statistics or other test results, including acceptance criteria and any additional information supporting the appropriateness of the characterized performance

The study evaluated AI algorithm performance for four abdominal measurements: kidney sagittal length, kidney transverse width, kidney transverse height, and spleen length. Table 1 presents the comparative clinical measurement results between AI Auto Measure Abdomen and the ground truth. Table 2 provides the Bland-Altman Limits of Agreement (LoA) analysis of the AI Auto Measure Abdomen in relation to the ground truth, with reference to established acceptance criteria.

Table 1. Clinical measurement summary for AI Auto Measure Abdomen and Ground Truth

Measurement	AI Auto Measure (cm) Mean ± SD (Min, Max)	Ground Truth (cm) Mean ± SD (Min, Max)
Kidney Sagittal Length	10.55 ± 1.20 (7.54, 14.80)	10.50 ± 1.17 (7.20, 14.13)
Kidney Transverse Width	5.19 ± 0.60 (3.25, 7.26)	5.17 ± 0.71 (3.62, 7.30)
Kidney Transverse Height	5.11 ± 0.80 (2.95, 7.71)	5.10 ± 0.83 (2.84, 7.76)

Measurement	AI Auto Measure (cm) Mean ± SD (Min, Max)	Ground Truth (cm) Mean ± SD (Min, Max)
Spleen Length	10.77 ± 2.41 (6.08, 20.36)	10.53 ± 2.39 (5.52, 19.59)

Table 2. Primary endpoint: Bland-Altman limits of agreement (in percentage) for clinical measurements between AI Auto Measure Abdomen and Ground Truth

Measurement	Mean Difference ± SD	95% LoA	95% CI of LoA	Acceptance Criteria
Kidney Sagittal Length	0.46% ± 3.51%	(-6.41%, 7.33%)	(-7.10%, 8.02%)	[-14.3%, 14.3%]
Kidney Transverse Width	0.26% ± 8.79%	(-16.97%, 17.49%)	(-18.77%, 19.29%)	[-33.7%, 33.7%]
Kidney Transverse Height	0.54% ± 6.36%	(-11.92%, 13.00%)	(-13.22%, 14.30%)	[-30.1%, 30.1%]
Spleen Length	2.34% ± 4.90%	(-7.26%, 11.94%)	(-8.63%, 13.32%)	[-15.9%, 15.9%]

The primary endpoint analysis indicated a strong concordance between measurements generated by the AI Auto Measure Abdomen algorithm and those obtained manually by clinical experts (serving as ground truth). The confidence intervals (CI) for the LoA satisfied the predefined acceptance criteria established for the study.

b. The number of individual patients from whom the images were collected

A total of 150 subjects (i.e. 150 ultrasound exams) from whom images were collected for the performance validation study.

c. The number of samples, if different from above, and the relationship between the two

A total of 292 images in kidney longitudinal view were used for kidney length measurement
A total of 271 images in kidney transverse view were used for kidney width and height measurement
A total of 145 images in spleen sagittal view were used for spleen length measurement.

d. Demographic distribution including sex, age, and ethnicity

- Age (y): 58.59 ±14.70 (Mean ± SD), range (22, 85)
- Gender: Female 50%; Male 50%
- BMI (kg/m^2): 26.20 ± 4.74 (Mean ± SD), range (17.97, 48.40)
- Ethnicity:
  - American Indian 0.67 %
  - Asian 31.33 %
  - Black or African American 3.33 %
  - Hispanic 0.67 %
  - White 64.00 %

e. Information about clinical subgroups and confounders present in the dataset

Validation images were obtained from subjects who represent the intended population with a broad range of demographics, body types and organ measurement values.

More specifically, patients from all BMI categories: Underweight (<18.5), Healthy Weight (18.5 to <25), Overweight (25 to <30), and Obesity (≥30) were included to ensure balanced body habitus representation.

Additionally, the study included patients referred for abdominal or renal exams and healthy volunteers, with datasets reflecting different clinical statuses to maintain clinical relevance:

Kidney Clinical Status

- Abnormal 22.00 %
- Normal 78.00 %

Spleen Clinical Status

- Abnormal 1.33 %
- Normal 98.67 %

f. Information about equipment and protocols used to collect images

Adults (≥18 years) were enrolled at three clinical sites, including patients referred for abdominal or renal ultrasound and healthy volunteers. Imaging was performed using Philips EPIQ and Affiniti systems with C5-1 and C9-2 transducers. Each site followed a standardized study protocol for data collection.

g. Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)

Three clinical experts independently carried out manual measurements during the performance assessment. The average values obtained from their measurements served as the ground truth and were used to evaluate AI performance. All three experts are registered clinical sonographers with ten or more years of experience in general imaging and abdominal imaging, and each holds active certification by American Registry for Diagnostic Medical Sonography (ARDMS).

h. Description of how independence of test data from training data was ensured.

The datasets used in the validation study and for regulatory clearance were distinct from those employed during algorithm training. Data independence between performance validation and model development was ensured by sourcing data from different clinical sites, different time periods and different ultrasound systems.

Since this is a software-only change 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 proposed EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound with Auto Measure Abdomen. The transducer patient contact materials and manufacturing processes are not impacted by the release of the proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound with Auto Measure Abdomen.

VIII. Clinical Data

The proposed device in this premarket submission, EPIQ Series Diagnostic Ultrasound Systems and Affiniti Series Diagnostic Ultrasound Systems with Auto Measure Abdomen software application, did not require clinical studies to support substantial equivalence.

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

The proposed device, *EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System*, has a predicate device which is legally marketed. Both subject device and predicate devices have the same intended use. The technological differences between the proposed device and the predicate devices do not raise new or different questions of safety and effectiveness.
Both the proposed device and the predicate were tested with the same types of non-clinical testing methods and follow the same set of standards.
Therefore, the proposed device *EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System* is substantially equivalent to the predicate devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness."