December 12, 2024

Philips Ultrasound LLC
Chanrasmey White
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021

Re: K242020
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: November 12, 2024
Received: November 12, 2024

Dear Chanrasmey White:

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

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

510(k) Number *(if known)*
K242020

Device Name
EPIQ Series Diagnostic Ultrasound System;
Affiniti Series Diagnostic Ultrasound System

Indications for Use *(Describe)*
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.

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

510(k) Summary #K242020

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

Date Prepared: December 9, 2024

I. Submitter

Manufacturer Name and Address	Philips Ultrasound LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA
Contact Information	Chanrasmey White Senior Regulatory Affairs Specialist 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA smey.white@philips.com 1-207-249-5503
Secondary Contact	Amy Yang Regulatory Affairs Director 22100 Bothell Everett Hwy Bothell, WA 98021-8431 USA amy.yang@philips.com 1-304-266-8208

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	K240850; EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound System

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the Auto ElastQ software feature onto the EPIQ and Affiniti Series Diagnostic Ultrasound Systems. The proposed EPIQ Series Diagnostic Ultrasound System and Affiniti Series Diagnostic Ultrasound Systems with new Auto ElastQ software feature, which is a workflow-enhancement software feature, is equivalent to predicate device, K240850.

The Auto ElastQ software feature is intended to assist users in making stiffness measurements using 2D-SWE in the liver by recommending specific frames and ROI positions to the user.

No hardware changes to the EPIQ or Affiniti Systems are required when using the Auto ElastQ software feature, and existing, commercialized Philips transducers are used for the Auto ElastQ software feature. The feature is supported by EPIQ and Affiniti models running software version 12.0.

IV. Indications for Use

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.

V. Comparison of Technological Characteristics with the Predicate

The purpose of the submission is to introduce the Auto ElastQ software feature onto the EPIQ and Affiniti Series Diagnostic Ultrasound Systems. 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 (K240850).

Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Proposed Devices	EPIQ Series Diagnostic Ultrasound System Affiniti Diagnostic Ultrasound System (K240850) Predicate Device	Comparison
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
Marketing Name of Application	Auto ElastQ	ElastQ	Subject of this submission
Application Description	The Auto ElastQ software feature is intended to assist the user in making liver stiffness measurements using 2D-SWE through recommended particular frames and ROI positions to the user. The system software will select up to three frames that are assessed to be the most stable and present these to the user. The circle ROI will be launched in the locations that are identified to be homogenous and temporally stable.	The ElastQ feature ("manual workflow") is a tool for measuring the stiffness of the target organ (liver) which requires the user to review a loop of elastography images displayed on the system and uses the trackball to cine to the frame(s) that are visually perceived to be the most stable. The circle ROI is then launched in the center of the shear wave imaging box, and the user manually positions the ROI within the box in a location that appears to be homogenous and representative of the tissue in the entire box.	Subject of this submission The difference between the predicate and the subject device is: The proposed Auto ElastQ feature recommends particular frames and ROI locations that are assessed to be most stable homogenous to the user. The predicate device requires users to review a loop of elastography images and then use the trackball to cine to the frames that are visually perceived to be the most stable. Then the user must manually positions the ROI in a location that appears to be most stable and homogenous.

Feature	EPIQ Series Diagnostic Ultrasound System Affiniti Series Diagnostic Ultrasound System Proposed Devices	EPIQ Series Diagnostic Ultrasound System Affiniti Diagnostic Ultrasound System (K240850) Predicate Device	Comparison
User Interface Presentation	The Auto ElastQ workflow analyzes the frames present in the cineloop buffer. The system software will automatically cine to three frames that are assessed to be the most stable and present these to the user. The measurement ROI will automatically launch and be placed on locations identified to be homogeneous and temporally stable. Even though the Auto ElastQ feature will suggest a particular ROI placement, the user must inspect the results and ensure that it meets intended clinical use. Otherwise, the user can make adjustments to what the feature proposes, by either selecting a different frame or a different ROI position.	In the current released software ("manual workflow"), the user reviews a loop of elastography images displayed on the system display and then uses the trackball to cine to the frame(s) that are visually perceived to be the most stable. The circle ROI is then launched in the center of the shear wave imaging box, and the user manually positions the ROI within the box in a location that appears to be homogeneous and representative of the tissue in the entire box.	Subject of this submission The proposed Auto ElastQ will provide a recommendation to the user where the predicate device requires the user to navigate the system manually.
Compatible transducers	Auto ElastQ Feature: C5-1	ElastQ Feature: C5-1	Identical, no new transducers or modes are being introduced in this submission.
Measurements Performed	The Auto ElastQ feature calculates stiffness measurements based on selected frames and ROI positions recommended to the user or based on user adjustments to what the feature recommended.	The ElastQ feature calculates stiffness measurements based on the manually selected frames and ROI positions.	No new measurements are being introduced in this submission. The subject of this submission is to provide workflow enhancements.
Application performance	A retrospective data analysis study was conducted to evaluate the performance of the Auto ElastQ software compared to manual measurements performed by expert readers. The results demonstrated high agreement of Auto ElastQ algorithm-generated measurements, based on statistical analysis, with manual elastography measurements.	N/A – the equivalent functionality is performed manually by the users to select the most appropriate frames and ROI positions.	Subject of this submission

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 of the EPIQ Series and Affiniti Series Diagnostic Ultrasound Systems was tested in accordance with Philips Internal Procedures. The design process incorporated IEC 62304 Medical Device Software – Software life cycle processes, 2006 + A 2015 and Risk Management procedures were applied in accordance with ISO 14971 Medical devices - Application of risk management to medical devices, to ensure the continued safe and effective performance. All software verification tests met the acceptance criteria.

Non-clinical verification testing was conducted to address the change and performance test data were provided to support the introduction of the subject software algorithm for the Auto ElastQ software feature. All software verification tests met the acceptance criteria.

A retrospective data analysis study was conducted to evaluate the performance of the Auto ElastQ software compared to manual measurements performed by expert readers, with the manual measurements used as ground truth for the study. The results demonstrated high agreement of Auto ElastQ algorithm-generated measurements with manual elastography measurements, meeting the acceptance criteria for the study.

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 Auto ElastQ software feature meets the intended use. 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, product codes.
- Have identical software.
- Are introducing no new hardware or 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 Auto ElastQ feature recommends particular frames that are assessed to be most stable and ROI locations that are assessed to be the most stable and homogenous to the user, where the predicate devices require users to review a loop of elastography images then uses the trackball to cine to the frames that are visually perceived to be the most stable and manually positions the ROI in a location that appears to be most stable and homogenous.

Therefore, the proposed Auto ElastQ feature for the EPIQ and Affiniti Series Diagnostic Ultrasound Systems is substantially equivalent to the predicate EPIQ and Affiniti Series Diagnostic Ultrasound Systems in terms of safety and effectiveness.