



September 25, 2026

Philips Ultrasound, LLC
Swetha Paritala
Principal Regulatory Affairs Specialist
22100 Bothell Everett Hwy.
Bothell, Washington 98021

Re: K262548

Trade/Device Name: EPIQ Inspira 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, LLZ

Dated: July 23, 2026

Received: July 23, 2026

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 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,

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.

K262548

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Please provide the device trade name(s).

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EPIQ Inspira Series Diagnostic Ultrasound System;
Affiniti Series Diagnostic Ultrasound System

Please provide your Indications for Use below.

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EPIQ Inspira Indications for Use:

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 (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color M Mode, Power Doppler, 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 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 Doppler, Power Doppler, 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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Please select the age group(s) for which the device(s) is to be used.

- ☒ Neonates/Newborns (Birth to < 29 days old)
☒ Infants (29 days old to < 2 years old)
☒ Children (2 years old to < 12 years old)
☒ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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Traditional 510(k)
EPIQ Inspira Series Diagnostic Ultrasound system
Affiniti Series Diagnostic Ultrasound system
510(k) Summary

K262548

510(k) Summary

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

510(k) Number:

Date Prepared: 25 September 2026

I. Submitter

Manufacturer Name and Address

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II. Device

Proprietary Name

EPIQ Inspira Series Diagnostic UltrasoundSystem;
Affiniti Series Diagnostic Ultrasound System

Common Name

Diagnostic Ultrasound System and Transducers;
System, Imaging Processing, Radiological

Device Class

Class II

Review Panel

Radiology

Classification Regulation

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
System, image processing, radiological	892.2050	LLZ
Diagnostic Intravascular Catheter	870.1200	OBJ*

*EPIQ only, compatibility with Verisight ICE catheter (cleared under K200812)



Predicate Devices

Primary: EPIQ and Affiniti Series Diagnostic Ultrasound System; K253595
Secondary: QLAB Advanced Quantification Software 13.0 (AutoStrain LA); K190913

III. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce 2D Auto LA, an automated left atrial quantification software feature, for use on the EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems, as well as the introduction of the EPIQ Inspira Series as a new variant within the EPIQ Series Diagnostic Ultrasound System family.

The Philips EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems are general-purpose, software-controlled diagnostic ultrasound systems intended for diagnostic ultrasound imaging and fluid flow analysis of the human body and support multiple clinical applications, including adult cardiac imaging.

2D Auto LA is an assistive, user-initiated software feature that supports routine adult transthoracic echocardiography (TTE) workflow by providing automated quantification of left atrial (LA) size and function from retrospectively acquired two-dimensional echocardiographic image loops, including apical four-chamber (A4C) and apical two-chamber (A2C) views. The feature provides biplane left atrial strain (LASr, LAScd, LASct) and left atrial end-systolic volume (ESV) measurements using established methods. The feature supports workflow efficiency through automation of measurements while maintaining a clinician-in-the-loop workflow.

2D Auto LA includes the following principal functional components:

- Automated detection of left atrial endocardial borders using previously cleared AI-based contour detection
- Speckle tracking-based strain analysis for computation of left atrial strain parameters (reservoir, conduit, and contraction phases)
- Biplane LA volume calculation using Simpson's method based on A4C and A2C views
- Visualization of results including strain curves, contour overlays, and numerical outputs
- User interaction capabilities for editing contours, adjusting cardiac cycle selection, and refining analysis parameters prior to finalization

The user remains responsible for selection of appropriate image data, verification of image quality, and review of automated outputs. The user may accept, edit, or reject measurements prior to clinical use. If automated analysis is not satisfactory, the user can perform manual adjustments or revert to standard manual measurement workflows.

2D Auto LA is compatible with the EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems and operates with supported adult cardiac transducers. The relevant imaging mode for the feature is two-dimensional (2D/B-mode) echocardiographic imaging.

IV. Intended Use & Indications for Use

The intended use of EPIQ Inspira and Affiniti series Ultrasound Diagnostic System is diagnostic ultrasound imaging and fluid flow analysis of the human body.

System Level (i.e., EPIQ Inspira series Diagnostic Ultrasound System) Indications for Use:

The intended use of EPIQ Inspira Series 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 (3D/4D), M Mode, PW Doppler, CW Doppler, Color Doppler, Color

M Mode, Power Doppler, 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 responsibility for sound clinical judgement and best clinical procedure.

Note: There are no changes to the EPIQ Inspira Ultrasound System Indications for Use due to the modification of the 2D Auto LA software applications.

System Level (i.e., Affiniti Diagnostic Ultrasound System) Indications for Use:

The intended use of Affiniti Series Ultrasound Diagnostic 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 responsibility for sound clinical judgement and best clinical procedure.

Note: There are no changes to the Affiniti Ultrasound System Indications for Use due to the modification of the 2D Auto LA software application.

V. Comparison of Technological Characteristics with the Predicate

The subject devices maintain the same intended use as the predicate devices, with no changes to the diagnostic purpose or supported clinical applications. Both the subject and predicate devices are indicated for diagnostic ultrasound imaging and fluid flow analysis and are intended for use by appropriately trained healthcare professionals in the same clinical environments.

The EPIQ Inspira Series Diagnostic Ultrasound System is identical to the predicate EPIQ and Affiniti Series Diagnostic Ultrasound System (K253595) in terms of hardware platform, software architecture, imaging modes, and fundamental operating principles. The subject and predicate devices share the same FDA device classification and product codes. Acoustic output characteristics are equivalent, and there are no changes to transducer compatibility, patient-contacting materials, packaging, or manufacturing processes. Accordingly, no new risks are introduced at the system level.

At the feature level, 2D Auto LA is an AI-assisted cardiac ultrasound quantification tool introduced as a software-only feature on the Philips EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems. The 2D Auto LA builds upon and integrates functionalities from its predicate devices, AutoMeasure (K253595) and QLAB Advanced Quantification Software (AutoStrain LA, K190913). All features are designed to support quantitative assessment of left atrial (LA) size and function during routine

adult transthoracic echocardiography (TTE) exams while maintaining user control and clinical oversight.

The predicate AutoStrain LA provides speckle tracking–based strain analysis of the left atrium, while AutoMeasure enables automated measurement of cardiac structures including left atrial volumes. The 2D Auto LA feature integrates these capabilities into a unified workflow, providing automated and semi-automated biplane LA strain and volume measurements derived from apical four-chamber (A4C) and apical two-chamber (A2C) views. Similar to the predicate devices, the subject device operates using AI-assisted, non-adaptive (locked) algorithms and requires user review, editing, and acceptance of all outputs prior to clinical use.

The primary technological difference between 2D Auto LA and its predicate devices lies in the integration of previously cleared functionalities into a single application and the extension to biplane LA strain and volume analysis. This integration improves workflow efficiency but does not modify image acquisition, underlying image data, or fundamental measurement principles. The user retains full control to review, accept, reject, or manually adjust all generated outputs using existing system tools.

There are no changes to system hardware, imaging modes, or clinical workflow as a result of introducing 2D Auto LA. The feature operates entirely within the existing ultrasound system architecture and includes safeguards that allow users to revert to manual operation if needed. The addition of 2D Auto LA does not introduce new indications for use, new diagnostic claims, or changes to device classification.

Verification and validation activities, including software verification and system-level testing performed in accordance with IEC 62304 and ISO 14971, demonstrate that the subject device performs as intended and meets applicable safety and performance requirements.

Feature-Level Comparison - Summary Table

Feature	2D Auto LA (Subject Device)	AutoMeasure (K253595)	AutoStrain LA (K190913)	Comparison
Primary Function	LA strain + volume (biplane)	Cardiac measurements (incl. LA volume)	LA strain analysis	Integrated functionality
Workflow	Automated + user review	Semi-automated	Semi-automated	Similar
AI Usage	AI-assisted, locked	AI-assisted	AI-assisted	Identical behavior
Outputs	Strain + ESV (biplane)	Volume measurements	Strain parameters	Combined outputs
User Control	Review/edit/accept	Review/edit	Review/edit	Identical
Diagnostic Role	Decision-support only	Decision-support	Decision-support	Identical

Based on the similarities in intended use, system architecture, and technological characteristics, and considering that the differences are limited to software integration and workflow optimization that do not impact clinical interpretation or system operation, the subject device is substantially equivalent to the predicate devices.

VI. Safety Considerations

The proposed EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems, including the 2D Auto LA software functionality 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 (February 2023)*. The safety considerations of the predicate devices are applicable since the subject devices, at a system level, are identical systems with the addition of a new trade name and software-only functionality.

VII. Nonclinical Performance Data

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

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic and essential performance
- IEC 60601-1-2: 2014+AMD1:2020 Medical Electrical Equipment – Part 1-2: General requirements for safety; electromagnetic compatibility – requirements and tests
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
- IEC 60601-2-37:2024 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304:2006+AMD1:2015 Medical Device Software – Software life cycle process
- IEC 62366-1:2015+AMD1:2020 Medical devices – Application of usability engineering to medical devices
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of the subject device include but are not limited to the following:

- Requirements Review
- Risk Analysis and Risk Management Review
- Product Specification Review
- Design Review
- Software verification specific to 2D Auto LA functionality

VIII. Clinical Data

A retrospective clinical performance study was conducted to evaluate the performance of the 2D Auto LA application for automated and semi-automated quantification of left atrial (LA) end-systolic volume (ESV) and left atrial strain reservoir at end diastole (LASr ED) on Philips EPIQ Inspira and Affiniti Diagnostic Ultrasound Systems. The study included 217 transthoracic echocardiography (TTE) examinations obtained from 217 adult subjects representing a broad range of demographic and clinical characteristics. Of these examinations, 170 were included in the LA ESV analysis subset and 190 were included in the LA strain analysis subset. Ground truth measurements were established using qualified sonographer assessments and averaged across three independent blinded reviewers.

The study was conducted at two clinical sites and utilized predefined procedures to minimize bias, including independent review, blinded assessments, and washout periods between evaluation steps. Two co-primary endpoints were evaluated using Bland-Altman agreement analyses comparing 2D Auto LA measurements with the reference standard for biplane LA ESV and biplane LASr ED. Predefined acceptance criteria were $\pm 46\%$ for LA ESV and $\pm 28\%$ for LASr ED.

The results demonstrated that both co-primary endpoints met their predefined acceptance criteria. For biplane LA ESV, the lower and upper limits of agreement were -11.10% and 21.97% , respectively. For biplane LASr ED, the lower and upper limits of agreement were -5.99% and 11.05% , respectively. These results were well within the prespecified acceptance limits. Exploratory subgroup analyses across age, gender, BMI, ethnicity, and transducer type demonstrated performance generally consistent with the primary analyses.

The study demonstrated clinically relevant and meaningful performance of the 2D Auto LA application for quantification of left atrial size and function. Successful achievement of both co-primary endpoints supports the safety and effectiveness of the software and demonstrates performance comparable to qualified human observers. The results support the clinical acceptability of 2D Auto LA for use as a decision-support tool in adult transthoracic echocardiographic assessment of the left atrium

IX. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

X. Conclusion

The proposed devices, consisting of the 2D Auto LA feature implemented on the Philips EPIQ Inspira Series and Affiniti Series Diagnostic Ultrasound Systems, have been evaluated for substantial equivalence in accordance with the FDA guidance *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"* (issued July 28, 2014), as well as applicable FDA considerations for artificial intelligence-enabled device software functions as described in the FDA draft guidance *"Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations,"* (issued January 05, 2025), which outlines recommended documentation and evaluation approaches to support the assessment of safety and effectiveness of AI-enabled devices.

The predicate devices are legally marketed. The intended use and indications for use remain unchanged. The EPIQ Inspira Series is a branding update to an existing FDA-cleared ultrasound platform with identical hardware and software architecture, and the 2D Auto LA does not alter the diagnostic purpose or clinical applications of the system.

The EPIQ Inspira and Affiniti Series maintain the same hardware platform, software architecture, imaging modes, acoustic output characteristics, and transducer compatibility as the predicate devices. The primary technological difference is the addition of 2D Auto LA, an AI-assisted software feature that automates portions of the left atrial quantification workflow using previously cleared technologies, including AI-based border detection, speckle tracking strain analysis, and Simpson-based volume calculations.

2D Auto LA uses a fixed, non-adaptive algorithm to provide automated and semi-automated left atrial strain and volume measurements from two-dimensional echocardiographic images. Users retain responsibility for reviewing and confirming all results and may edit contours and measurements based on clinical judgment.

Risk management activities conducted in accordance with ISO 14971 demonstrated that identified risks were adequately mitigated. Verification, validation, and performance testing demonstrated that 2D Auto LA met all predefined acceptance criteria. In a retrospective validation study of 217 transthoracic echocardiography examinations, both co-primary endpoints for biplane left atrial volume (ESV) and biplane left atrial strain (LASr ED) met predefined acceptance criteria, supporting the safety and effectiveness of the feature.

The EPIQ Inspira Series Diagnostic Ultrasound System is system-level equivalent to the EPIQ Series Diagnostic Ultrasound System (K253595), with no hardware modifications or changes to system electronics, user interface, transducer compatibility, or technical specifications. Therefore, the EPIQ Inspira and Affiniti Series Diagnostic Ultrasound Systems with 2D Auto LA are substantially equivalent to the identified predicate devices with respect to intended use, technological characteristics, safety, and effectiveness.