June 29, 2026

Philips Ultrasound, LLC
Irma Sandoval-Watt
Senior Regulatory Manager
22100 Bothell Everett Hwy.
Bothell, Washington 98021

Re: K260667
Trade/Device Name: Alturion 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
Dated: May 29, 2026
Received: June 1, 2026

Dear Irma Sandoval-Watt:

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.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K260667

Device Name

Alturion Series Diagnostic Ultrasound System

Indications for Use *(Describe)*

The Alturion Series Diagnostic Ultrasound System is indicated for diagnostic ultrasound imaging and fluid flow analysis of the human body in 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), 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 the Alturion Series Diagnostic Ultrasound System 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 summary of safety and effectiveness information is submitted in accordance with 21 CFR §807.92.

510(k) Number: K260667

1. Submitter's name, address, telephone number, contact information

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Date Prepared: 27 Jun 2026

2. Name of the device, including the trade of proprietary name if applicable, the common or usual name, and the classification name, if known:

Proprietary Name: *Alturion Series Diagnostic Ultrasound System*

Common Name: Diagnostic Ultrasound System and Transducers

Regulatory Description:

Classification Description	21 CFR §	Product Code
Primary		
Ultrasonic pulsed doppler imaging system	892.1550	IYN
Secondary		
Ultrasonic pulsed echo imaging system	892.1560	IYO
Diagnostic ultrasonic transducer	892.1570	ITX
Medical image management and processing system	892.2050	QIH

Device Class: Class II

Review Panel: Radiology

Predicate Device: K243794, Affiniti Series Diagnostic Ultrasound System

Reference Device:	K231190, Epiq Series Diagnostic Ultrasound System K253595, Epiq Series Diagnostic Ultrasound System and Affiniti System Diagnostic Ultrasound System K231966, LOGIC E10 (GE Medical Systems Ultrasound and Primary Care Diagnostic, LLC),

3. Device Description

The Philips *Alturion Series Diagnostic Ultrasound System* is a general purpose, software controlled, diagnostic ultrasound system. Its functions are to acquire ultrasound data and to display the data in various modes of operation. The system consists of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics, and the transducer connection points. In addition to the physical knobs and buttons of the main control panel, the user interface consists of a touch screen with soft key controls. The transducers connect to the system console and facilitate ultrasound scanning of patients.

The *Alturion Series Diagnostic Ultrasound System* is considered a high-end refresh of the current Affiniti Series Diagnostic Ultrasound System and will be available in two configurations. At its core, the *Alturion Series Diagnostic Ultrasound System* is based on the Affiniti Series. Thus, enabling *Alturion Series* to use the same acoustic capabilities, and common software architecture as the Affiniti Series. The *Alturion Series Diagnostic Ultrasound System* is similar to other Philips ultrasound systems, most notably Affiniti Series Diagnostic Ultrasound System (K243794) in terms of indications for use, design, and fundamental technological characteristics.

The AI Auto Measure Abdomen feature in the *Alturion Series* aims to improve workflow efficiency by automating selected measurements required for routine abdominal exams. The Auto Measure Abdomen feature is designed to provide semi-automated and editable measures of abdominal organs such as kidney and spleen. The software feature offers to semi-automatically perform measurements for the user, who can always adjust caliper positions or make additional manual measurements. The Auto Measure Abdomen feature is available in C5-1 and C9-2 transducers only. This AI software feature is supported in all configurations of *Alturion Series Diagnostic Ultrasound Systems* running software version 14.0 or higher. The eV14-2v is a broadband, endocavitary Pure Wave transducer with elevation focus. The transducer eV14-2v includes a curved linear array with 6 MHz center frequency and 10.5 mm azimuth radius of curvature. The array has a total of 436 elements arranged in 3 rows of 218 elements. This transducer is supported in all configurations of *Alturion Series Diagnostic Ultrasound System*.

4. Indications For Use

The *Alturion Series Diagnostic Ultrasound System* is indicated for diagnostic ultrasound imaging and fluid flow analysis of the human body in 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), 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 the *Alturion Series Diagnostic Ultrasound System* 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.

5. Technological Comparison to Predicate Devices

The purpose of the submission is to introduce a new system to the Philips ultrasound systems portfolio, *Alturion Series Diagnostic Ultrasound System*, an AI Auto Measure Abdomen software feature, and a new transducer, eV14-2v.

The AI Auto Measure Abdomen feature was most recently cleared in K253595. The AI Auto Measure feature is for cardiac was cleared in the predicate device (K243794). A performance study for validation was conducted for Auto Measure Abdomen that includes patients scanned by both C5-1 and C9-2.

All comparison points between the new transducer, eV14-2v and the predicate 3D9-3v transducer are either same or equivalent to predicate. See the tabular table below for more details.

Table 1: Comparison of subject device, *Alturion Series Diagnostic Ultrasound System* to the current marketed predicate to the addition of a new transducer, eV14-2v.

Feature	**Alturion Series Diagnostic Ultrasound System and eV14-2v Transducer** **Subject Device**	**Affiniti Series Diagnostic Ultrasound System and 3D9-3V Transducer K243794** **Predicate Device**	**Comparison**
Scientific Technology	Ultrasound imaging	Ultrasound imaging	Same as predicate
Users	Trained healthcare professionals, sonographers, physicians, and biomedical engineers who operate and maintain the product.	Trained healthcare professionals, sonographers, physicians, and biomedical engineers who operate and maintain the product.	Same as predicate
Use Environment	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Same as predicate
Transducer Model	Endocavitary Curved Linear	Endocavitary Curved Linear	Same as predicate
Indications for Use	Fetal/OB; Fetal Echo; Trans-vaginal; GYI; Urology	Fetal/OB; Fetal Echo; Trans-vaginal; GYI; Urology	Same as predicate
Acoustic Output	Ispta .3 ≤ 720 (mW/cm²) TI ≤ 6.0 MI ≤1.9	Ispta .3 ≤ 720 (mW/cm²) TI ≤ 6.0 MI ≤1.9	Same as predicate
Acoustic Working Frequency	Center Frequency 6.1 MHz	Center Frequency 5.7 MHz	Equivalent to predicate
Geometrical Configuration	Curved Linear Array	Curved Linear Array	Same as predicate
Total Number of Elements	436 addressable elements connected to form dual aperture array with 218 elements per aperture	128	Different than predicate. The higher number of elements allows improved image quality by an increased field of view, better resolution, reduced clutter with elevation focus.

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Feature	Alturion Series Diagnostic Ultrasound System and eV14-2v Transducer Subject Device	Affiniti Series Diagnostic Ultrasound System and 3D9-3V Transducer K243794 Predicate Device	Comparison
Field of View (FOV)	180 degrees	155.5 degrees	Different from predicate. The higher FOV allows visualization of larger anatomical areas or pathologies in a single image.
Transducer Modes of Operation	B (2D); M-mode; PW Doppler; 3D/4D; Color; MPR	B, M PWD, Color, 3D/4D; Doppler; Combined	Equivalent to predicate
Tip Dimensions	Height: 25.3 mm Width: 25.3 mm Tip Diameter: 25.3 mm	Height: 26.3 mm Width: 26.3 mm Tip Diameter: 26.3 mm	Different from predicate. The differences are for improved patient comfort.
Connector	Cart-based system transducer connector	Cart-based system transducer connector	Same as predicate
Wight (including connector and cable)	< 0.9 kg	< 1.2 kg	Equivalent to predicate
Radiated Field Operating Controls	The transducer is controlled via the Ultrasound System's control panel.	The transducer is controlled via the Ultrasound System's control panel.	Same as predicate
Patient Contact Materials	Biocompatibility ISO 10993-1	Biocompatibility ISO 10993-1	Same as predicate
Transducer Maximum Surface Temperature (per IEC 60601-2-37, clause 201.11)	Still Air: 42.6°C Simulated Use 42.5°C	Still Air: 41.8°C Simulated Use: 42.5°C	Equivalent to predicate
Transducer Element Check Incorporated	Yes	Yes	Same as predicate
Transducer Provided Sterile	No	No	Same as predicate
Transducer Recommended use of covers	Yes	Yes	Same as predicate
Transducer Reusable	Yes	Yes	Same as predicate
Maximum Insertion Portion Width	25.3 mm	27.3mm	Equivalent to predicate The difference in width enhances patient comfort
Working Length (Intended Insertion Length)	150 mm	165 mm	Equivalent to predicate The difference in length enhances patient comfort
Transducer cleaning and disinfection instructions provided	Yes	Yes	Same as predicate
Professional Use	Yes	Yes	Same as predicate
Transducer Packaging	Transducer placed in a cardboard box with internal foam	Transducer placed in a cardboard box with internal foam	Same as predicate
510(k) Track	Track 3	Track 3	Same as predicate

Table 1 – Comparison of subject device, Alturion Series Diagnostic Ultrasound System to the current marketed predicate to the addition of a new transducer, eV14-2v.

For testing, all pre-determined acceptance criteria were met as per the supporting evidence provided as part of the verification report with this 510(k)-submission including Biocompatibility, EMC, Safety testing, Acoustic output, Design Qualification Test (DQT), Patient contact surface verification. The results of these tests show that the subject device, *Alturion Series Diagnostic Ultrasound System* meets the intended use.
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 and product codes.
- Have identical software architecture.
- Have identical hardware and imaging modes.
- Have equivalent acoustic output characteristics.
- Meet biocompatibility requirements per ISO 10993-1.
- Have equivalent transducer modes of operations.
- Have acoustic output levels within the Track 3 FDA limits and in accordance with IEC 60601-2-37.

6. Safety Considerations

The proposed *Alturion Series Diagnostic Ultrasound System* including AI Auto Measure Abdomen feature software application, and new transducer, eV14-2v, and compatible transducers are all Track 3 devices and comply with the reference standards and with the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, February 21, 2023.

7. Non-Clinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed subject device, *Alturion Series Diagnostic Ultrasound System*:

- 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 60601-2-18:2009 Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 62304:2006+AMD1:2015 Medical Device Software – Software life cycle process
- IEC 62359:2010+AMD1:2017 CSV Ultrasonics – Field Characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field
- IEC 62366-1:2015+AMD1:2020 Medical devices – Application of usability engineering to medical devices
- ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
- 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 *Alturion Series Diagnostic Ultrasound System* include but are not limited to the following:

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

Non-clinical testing also included the Performance Validation Study for the proposed Auto Measure Abdomen software application. 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.

Auto Measure Abdomen AI Feature Summary

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 2 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 2. 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)
Spleen Length	10.77 ± 2.41 (6.08, 20.36)	10.53 ± 2.39 (5.52, 19.59)

Table 2 – Clinical Measurement Summary for Auto Measure Abdomen AI and Ground Truth.

Table 3. Primary endpoint: Bland-Altman limits of agreements (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%]

Table 3 – Primary endpoint: Bland-Altman agreement for clinical measurements between Auto Measure Abdomen AI and Ground Truth.

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 ultrasound systems with C5-1 and C9-2 transducers as data deemed equivalent between Epiq, Affiniti and Alturion products given its shared codebase used for Auto Measure Abdomen. Each site followed a standardized study protocol for data collection.

g. Information about how 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 *Alturion Series Diagnostic Ultrasound System* with Auto Measure Abdomen AI feature. The transducer patient contact materials and manufacturing processes are not impacted by the release of the proposed *Alturion Series Diagnostic Ultrasound System* with Auto Measure Abdomen.

8. Clinical Data

The proposed *Alturion Series Diagnostic Ultrasound System* did not require clinical data for determination of substantial equivalence, with substantial equivalence being demonstrated based on the following attributes:
- Design features
- Indications for use

- Fundamental scientific technology
- Non-clinical performance testing
- Safety and effectiveness

9. Sterilization

The proposed *Alturion Series Diagnostic Ultrasound System* is not provided sterile; therefore, this is not applicable.

10. Conclusion

The subject device, *Alturion Series Diagnostic Ultrasound System*, has predicate devices which are legally marketed. Both subject device and predicate devices have the same intended use. The technological 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 *Alturion 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.