August 4, 2026

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

Re: K262311
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, POK
Dated: July 8, 2026
Received: July 8, 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,

Digitally signed by Michael D. O'hara -S
Date: 2026.08.04 14:43:44 -04'00'

For

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.	K262311

Please provide the device trade name(s).

Alturion Series Diagnostic Ultrasound System

Please provide your Indications for Use below.

The Alturion Series Diagnostic Ultrasound System is indicated for 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), 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.

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

510(k) Number: K262311

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

Manufacturer: Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

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Phone: 1-240-463-2613

Date Prepared: 07 July 2026

2. Name of the device, including the trade and 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
Radiological computer-assisted diagnostic software for lesions suspicious for cancer	892.2060	POK

Device Class: Class II

Review Panel: Radiology

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Predicate Device:	K260667 – Philips Alturion Series Diagnostic Ultrasound System
Reference Device:	K242130 – Koios Decision Support (DS)

3. Device Description

The purpose of this Special 510(k) premarket notification is to document adding a REST API client to connect the *Alturion Series Diagnostic Ultrasound System* (VM14.0) with Koios Decision Support (Koios DS), an AI/ML -based CADx software application. Koios DS will be offered as a licensed optional feature for Alturion.

Koios DS was cleared under K242130. Koios DS version 3.7.1 is integrated into the Philips *Alturion Series Diagnostic Ultrasound System*. Koios DS as an artificial intelligence (AI)/machine learning (ML)-enabled computer aided diagnosis (CADx) software application is intended for use as an adjunct to diagnostic ultrasound examination of lesions or nodules suspicious for breast or thyroid cancer. When an image of a breast or thyroid lesion is acquired on an ultrasound system, and sent over to the Koios DS workstation, the Koios application will process the image and respond by providing a result box with a diagnosis of the highlighted lesion. The results from the diagnosis can be displayed on the ultrasound system.

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

The Koios DS software is supported by all *Alturion Series Diagnostic Ultrasound System* running software version 14.0 or higher.

4. Indications For Use

There is no change to the intended use of the subject device, *Alturion Series Diagnostic Ultrasound System*, compared to the predicate device, *Alturion Series Diagnostic Ultrasound System*, with the integration of this optional Koios DS software feature.

The *Alturion Series Diagnostic Ultrasound System* is indicated for 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), 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.

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5. Technological Comparison to Predicate Devices

The purpose of this Special 510(k) premarket notification is to integrate the Koios Decision Support (DS), an artificial intelligence (AI)/machine learning (ML)-based computer-aided diagnosis (CADx) software application into the *Alturion Series Diagnostic Ultrasound System* (VM14.0).

The subject device and predicate device:

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

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

6. Safety Considerations

The subject device, *Alturion Series Diagnostic Ultrasound System* with Koios DS software integrated 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,* issued in 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 with* the Koios DS software feature integrated:

- 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 *Alturion Series Diagnostic Ultrasound System* with the integration of Koios DS, these activities include but are not limited to the following:

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

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

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

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

8. Clinical Data

The subject *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:

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

9. Sterilization

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

10. Conclusion

The subject device, *Alturion Series Diagnostic Ultrasound System* with Koios DS software feature implemented, has a predicate device which is legally marketed. Both subject device and predicate devices have the same intended use. The differences between the subject device and the predicate devices do not raise new or different questions of safety and effectiveness.

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

Therefore, the subject device *Alturion Series Diagnostic Ultrasound System* with Koios DS software feature implemented, is substantially equivalent to the predicate device in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.