May 5, 2026

Philips Ultrasound LLC
Gina Quiram
Senior Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021-8431

Re: K252558
Trade/Device Name: Lumify 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: April 2, 2026
Received: April 3, 2026

Dear Gina Quiram:

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
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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)*
K252558

Device Name
Lumify Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B(2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, and M-modes.

It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung.

The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

The Lumify Diagnostic Ultrasound System is intended to be used by qualified and trained healthcare professionals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Number: K252558

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

1. **Submitter's name, address, telephone number, contact person(s)**

Manufacturer:	Philips Ultrasound 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Person:	Gina Quiram Principal Regulatory Affairs Specialist gina.quiram@philips.com 310-745-2695
Secondary Contact:	Benny Lam Director of Regulatory Affairs Benny.Lam@philips.com 240-463-2679
Date Prepared:	05-May-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: Lumify Diagnostic Ultrasound System

Common Name: Diagnostic ultrasound system and transducers

Regulation Description:

Classification Description	21 CFR Section	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

Device Class: Class II

Classification Panel: Radiology

3. Device Description Summary

The Philips Lumify Diagnostic Ultrasound System (Lumify) is a mobile, durable, and reusable, software-controlled medical device, which is intended to acquire high-resolution ultrasound data and to display the data in B mode (2D), Pulsed Wave Doppler, Color Doppler, Combined (B+ Color), and M modes. The Lumify system is compatible with iOS and Android operating systems.

The Lumify Diagnostic Ultrasound System is compatible with iOS or Android operating systems. It utilizes:

1. A commercial off-the-shelf (COTS) iOS mobile item (smart phone or tablet)
2. The Philips Ultrasound Lumify software running as a medical device application on the COTS device
3. The Philips C5-2 Curved array USB transducer
4. The Philips L12-4 Linear array USB transducer
5. The Philips S4-1 Sector array USB transducer
6. Lumify Micro B Transducer Cable
7. Lumify Micro C Transducer Cable
8. Lumify USB-C to USB-C Transducer Cable
9. Lumify Power Module

Figure 1: Hardware components of Lumify Diagnostic Ultrasound System

The purpose of this Traditional 510(k) pre-market notification is to add software function *FAST Auto Assist* to Lumify Diagnostic Ultrasound System.

4. Indications for Use and Intended Use

There is no change to the clinical indication for Lumify Diagnostic Ultrasound System due to the addition of *FAST Auto Assist* software functions. The *FAST Auto Assist* software is limited to Android devices and for adult patients about the age of 18.

4.1 Indications for Use

The Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B(2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, and M-modes.

It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:

Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung.

The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.

The Lumify Diagnostic Ultrasound System is intended to be used by qualified and trained healthcare professionals.

4.2 Intended Use

The intended use of the product is to collect ultrasound image data that may be used by clinicians for diagnostic and procedural purposes. The product shall provide the ability for gathering clinically acceptable images and ultrasound data for the clinical presets and anatomies listed under the indications for use.

This product is intended to be installed, used, and operated only in accordance with safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces the user's responsibility for sound clinical judgement and best clinical procedure.

5. Substantially Equivalent Devices

Primary Predicate Device (system):	K223771, Philips Ultrasound – Lumify Diagnostic Ultrasound System
Secondary Predicate Device (system):	K233826 Kosmos Diagnostic Ultrasound System

6. Technological Comparison to Predicate Devices

There is no change in the intended use, technological characteristics of the proposed subject device when compared to the predicate.

Substantial equivalency tabulations and discussion of the primary standard features of the proposed subject device and predicate device at the system level is provided in **Table 1.**

Table 1: Summary of changes between proposed and predicate devices.

Standard Feature	Lumify Diagnostic Ultrasound System K252558 (Subject Device)	Lumify Diagnostic Ultrasound System K223771 (Primary Predicate Device)	Kosmos Diagnostic Ultrasound System K233826 (Secondary Predicate Device)	Comparison
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Ultrasound Imaging	Identical
Intended use	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Pulsed Wave, Color Doppler, Combined (B+Color), and M modes.	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Pulsed Wave, Color Doppler, Combined (B+Color), and M modes.	Kosmos is intended to be used by qualified and trained healthcare professionals in the clinical assessment for the following clinical applications by acquiring, processing, displaying, measuring, and storing ultrasound images, or synchronized ultrasound images, electrocardiogram (ECG) rhythms, and digital auscultation (DA) sounds and waveforms.	Remains unchanged from primary predicate
Indications for Use	Lumify Diagnostic Ultrasound System is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric,	Lumify Diagnostic Ultrasound System is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric,		Remains unchanged from primary predicate

Standard Feature	Lumify Diagnostic Ultrasound System K252558 (Subject Device)	Lumify Diagnostic Ultrasound System K223771 (Primary Predicate Device)	Kosmos Diagnostic Ultrasound System K233826 (Secondary Predicate Device)	Comparison
	Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung. The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung. The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.		
Modes of Operations	B (2D), Pulse Wave, Color Doppler, Combined (B+Color), and M modes	B (2D), Pulse Wave, Color Doppler, Combined (B+Color), and M modes	B-mode, M-mode, Color Doppler, Pulsed-Wave (PW) Doppler, Continuous-Wave (CW) Doppler combined modes of B+M and B+CD, B+PW, B+CW, and Harmonic Imaging.	Remains unchanged from primary predicate
Principles of Operation (Subject: *FAST Auto Assist)*	Lumify *FAST Auto Assist* is a software only feature. The core system software architecture remains unchanged. This additional feature is added to detect organs and respective zone in real-time during an abdominal FAST Exam. The software function detects and labels organs in the LUQ (Left Upper	Not Applicable This feature was not available with this version.	The Kosmos includes the Auto Anatomical Structure Labeling and View Identification, also referred to as AI FAST, software for automatic real-time detection and labeling of anatomical structures during image acquisition during cardiac, thoracic/lung, or	Similar to secondary predicate device. The subject device includes a subset of the secondary predicate device: real-time detection and labeling of the anatomical structures in the LUQ (Left Upper Quadrant), RUQ (Right Upper Quadrant), and SP (Supra-Pubic)

Standard Feature	Lumify Diagnostic Ultrasound System K252558 (Subject Device)	Lumify Diagnostic Ultrasound System K223771 (Primary Predicate Device)	Kosmos Diagnostic Ultrasound System K233826 (Secondary Predicate Device)	Comparison
	Quadrant), RUQ (Right Upper Quadrant), and SP (Supra-Pubic) regions that appear during an abdominal FAST exam scan.		abdominal ultrasound imaging.	regions.
Users	Lumify Ultrasound System is used by healthcare professionals.	Lumify Ultrasound System is used by healthcare professionals.	KOSMOS is intended to be used by qualified and trained healthcare professionals.	Remains unchanged from predicate device.
User Environment	The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Not applicable	Identical to primary predicate device
Transducers	S4-1 C5-2	S4-1 C5-2 L12-4	Not applicable	A subset of primary predicate's transducers. Only S4-1 and C5-2 work with ***FAST Auto Assist*** software function.
Patient Contact Materials	Not applicable. Transducers previously cleared.	Not applicable. Transducers previously cleared.	Not applicable	Remains unchanged from primary predicate
Primary Product Code	IYN	IYN	IYN	Remains unchanged from primary predicate
Secondary Product Code	IYO, ITX, QIH	IYO, ITX, QIH	DPS, DQD, ITX, IYO, QIH	Remains unchanged from primary predicate

7. Safety Considerations

The proposed Lumify Diagnostic Ultrasound System with software function *FAST Auto Assist* is Track 3 device and comply with the reference standards and with FDA ultrasound guidance document, "*Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Guidance for Industry and Food and Drug Administration Staff, February 21, 2023*".

8. Non-Clinical Performance Data

Non-clinical verification testing was conducted to address the system level requirements according to system and design specifications, and risk control measures. The activities to assure the safe and effective performance of the Lumify Diagnostic Ultrasound System with software function *FAST Auto Assist* included, but are not limited to, the following:

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

Biocompatibility testing is not needed for the subject Lumify Ultrasound System with *FAST Auto Assist* software function as this is a software only release. The transducers patient contact materials and manufacturing processes are not impacted by the release of the subject Lumify Ultrasound System with *FAST Auto Assist*, and all the transducers that are compatible with the software are already commercially available from Philips. Furthermore, no new hardware testing (such as IEC 60601-1, IEC 60601-2-37) was required since this change is software-based only.

Retrospective data analysis study evaluated the performance of artificial intelligence algorithms integrated into the Philips Lumify Diagnostic Ultrasound System for supporting automation of predicting abdominal zone and organs during FAST Exam scan.

The retrospective data analysis study evaluated the performance of the artificial intelligence algorithms integrated into the Philips Lumify Diagnostic Ultrasound System for organ and zone detection and labeling in the LUQ (Left Upper Quadrant), RUQ (Right Upper Quadrant), and SP (Suprapubic). Images were collected **from 82 individual patients** that were presented in the Emergency Department of suspected free fluid and eligible for FAST exam, and the study analyzed 229 video loops acquired during FAST exams. These video loops represented different abdominal zones and transducer types (sector and curvilinear), ensuring a robust dataset for evaluating the software's accuracy and reliability.

The independence of test data from training data was ensured by collecting data for the development and validation of the *FAST Auto Assist* software from completely independent clinical sites, involving different patients and users who acquired the data. Each subject received an ID that incorporated the clinical site identifier to simplify the data-separation process. Specifically, the test data was collected exclusively using the Lumify system, and the datasets used for test were separate from those used in software development. This separation created a strong distinction between the development and test datasets, ensuring no overlap. The subjects whose video loops were used in the study were 35.4% female. The age of the subjects included in the study ranged from 18-89 years with a BMI of 27.8 ± 6.1. Majority of subjects (59.8%) were white and non-Hispanic or Latino were 76.5%.

The retrospective study evaluated the performance of the *FAST Auto Assist* software in detecting abdominal zones and predicting organ labels using ultrasound videos acquired during FAST exams. The ground truth was established based on the majority consensus of the reviewers. The results from the primary endpoint demonstrated high accuracy, with an overall accuracy of 86.0% [95% CI 80.85%–90.24%], p-value = 0.0115, meeting the pre-defined acceptance criteria for the study. Both curvilinear and sector transducers individually exhibited high accuracy. Additional analysis across demographic variables, including gender, BMI, age, race, and ethnicity, demonstrated consistently high accuracy among all groups.

The secondary endpoint of the study was to evaluate the performance of predicting the location of the organ label by the *FAST Auto Assist* software for the respective organ compared with each reviewer. Results showed high agreement for the secondary endpoint of the study where the frame level accuracy of 83.0%-93.4% was achieved for labeling the various organs.

Sensitivity and specificity for the zone and organ detection were also evaluated. The sensitivity for zone detection ranged from 83.3% to 96.1%, and for organ detection ranged from 82.3% to 98.6%. The specificity for zone detection ranged from 90.2% to 96.0%, and for organ detection ranged from 89.0% to 96.0%.

9. Clinical Performance Data

The clinical performance of *the FAST Auto Assist* software was evaluated in a limited study involving 20 patients with diverse demographics. Both sector (S4-1) and curved (C5-2) transducers were used. Participants for the study had experienced physical trauma or acute medical conditions and were suspected of having free abdominal fluid. The software correctly identified zones and organs in real time with automatic zone detection accuracy between 85% and 95%. The sensitivity for zone detection ranged from 85.0% to 95.0% and for organ detection ranged from 84.2% to 90.0%. The specificity for zone detection ranged from 92.5% to 97.5% and for organ detection ranged from 95% to 97.6%. The study demonstrated that *FAST Auto Assist* performs as intended in clinical scenarios across a heterogeneous patient population, including patients with abnormalities and free fluid. Further, the clinical bench study demonstrates the safety and effectiveness of the software function *FAST Auto Assist* and confirms the device met the clinical user needs as intended.

10. Sterilization

Not applicable. The Lumify Diagnostic Ultrasound System's existing transducers, including L12-4, C5-2, and S4-1transducers are not supplied sterile.

11. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed subject device meets its intended use.

The changes made to the subject device do not affect the use of the device, nor do they introduce any new or significantly modified risks. The results of the relevant performance and compatibility tests support a determination that the proposed subject device does not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the primary predicate K223771, Philips Ultrasound – Lumify Diagnostic Ultrasound System in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.