December 22, 2025

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

Re: K252557
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: November 24, 2025
Received: November 24, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252557

Please provide the device trade name(s).

Lumify Diagnostic Ultrasound System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

TRADITIONAL 510(k)
Philips Ultrasound
Lumify Diagnostic Ultrasound System with Lung Application 3

510(k) Number: K252557

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 LLC 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Person:	Gina Quiram Principal Regulatory Affairs Specialist gina.quiram@philips.com Phone: 1-310-745-2695
Secondary Contact:	Priscilla Herpai Senior Regulatory Affairs Manager Priscilla.Herpai@philips.com Phone: 1-610-533-7984
Date Prepared:	July 30, 2025

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. Lung Application 3 Device Description Summary (Per 21 CFR 807.92)

The Lung Application 3 is a software-only functionality integrated into the Philips Lumify Diagnostic Ultrasound System, designed to support lung ultrasound examinations. It introduces two key features: pleural line assessment and lung image view quality assessment. The Pleural Line feature identifies and assesses the appearance of pleural lines as normal or irregular (defined as thickened, interrupted, fragmented, jagged, uneven, or otherwise non-smooth appearance on ultrasound). The lung view quality tool assesses the adequacy of ultrasound frames based on overall image appearance and the presence of any pleural lines. The application operates on a compatible Android-based commercial off-the-shelf device (e.g., tablet or smartphone) connected to Lumify transducers (C5-2, S4-1, and L12-4 models). It utilizes machine learning algorithms trained on a large dataset of expert-annotated lung ultrasound images to ensure accurate analysis. The workflow includes zone selection, image acquisition, navigation, review, and editing of results, with real-time feedback provided via visual indicators for image quality and pleural line analysis. The Lung Application 3 is intended for use by trained professionals in clinical settings to assist in evaluations of adult patients (18 years and older) with various pulmonary conditions. It does not introduce any new contraindications and is designed to comply with existing safety and operational standards.

Key Features:

- Software-based functionality for lung ultrasound enhancement.
- Pleural line classification as normal or irregular appearance.
- Lung view quality assessment for diagnostic adequacy.
- Real-time feedback via visual indicators.
- Machine learning-based algorithms for accurate image analysis.
- Compatibility with existing Lumify transducers and Android devices.

Intended Use:

The Lung Application 3 is intended to assist healthcare professionals by providing automated image processing to analyze ultrasound images for lung-related conditions. Specifically, it evaluates the adequacy of ultrasound frames for clinical interpretation and assesses the appearance of pleural lines as normal or irregular.

Essential Characteristics:

1. **Pleural Line Assessment:**
   - The application includes a feature to identify and evaluate pleural lines in ultrasound frames, categorizing their appearance on ultrasound as normal or irregular. The appearance of the pleural line may provide non-diagnostic, contextual information about lung condition when interpreted alongside other ultrasound features.

2. **Lung Image View Quality Assessment:**
   - The software assesses the quality of incoming ultrasound frames to determine their adequacy for clinical interpretation. It provides real-time feedback, with adequate frames indicated in green and inadequate frames in red, enabling users to adjust transducer positioning or acquisition settings as needed.

3. **Software Integration:**
   - The Lung Application 3 is fully integrated into the existing Lumify software platform, utilizing

the same hardware components (e.g., C5-2, S4-1, and L12-4 transducers) without introducing new risks or altering the system's core functionality.

4. **Cineloop-Level Reporting:**
   - The application provides assessments at the cineloop level, averaging results across frames.

5. **Safety and Effectiveness:**
   - The Lung Application 3 has been validated through performance testing, meeting all predefined acceptance criteria. It demonstrates substantial equivalence to the predicate device and does not raise new questions of safety or effectiveness.

In summary, the Lung Application 3 enhances the Lumify system by providing automated tools for pleural line assessment and lung image quality evaluation, supporting clinicians in assessing pulmonary conditions effectively and safely. The Lung Application 3 adheres to established safety protocols and does not alter the hardware functionality of the Lumify system. It is intended to be operated in accordance with user instructions provided in the product documentation.

3.1 Philips Lumify Diagnostic Ultrasound System

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 (iOS) 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 Lung Application 3 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 Lung Application 3 software functions.

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.

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

Predicate Device (system): K223771, Philips Ultrasound – Lumify 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 K# (K252557) (Subject Device)	Lumify Diagnostic Ultrasound System K223771 (Predicate Device)	Comparison
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Remains unchanged
Intended use	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.	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.	Remains unchanged
Indications for Use	Lumify Diagnostic Ultrasound System 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.	Lumify Diagnostic Ultrasound System 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.	Remains unchanged
Modes of Operations	B(2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, and M-modes	B(2D), Color Doppler, Combined (B+Color), Pulsed Wave Doppler, and M-modes	Remains unchanged

Standard Feature	Lumify Diagnostic Ultrasound System K# (K252557) (Subject Device)	Lumify Diagnostic Ultrasound System K223771 (Predicate Device)	Comparison
Principles of Operation	The pleural line tool detects and assesses the appearance of pleural lines in incoming ultrasound frames. The lung view quality tool indicates whether incoming ultrasound frames are adequate for supporting interpretation of lung features. Cineloop-level reporting is provided by averaging results from each frame. Both features allow manual adjustment of software results.	The B-lines tool detects B-lines in incoming ultrasound frames and classifies them as merged or not merged. Cineloop-level reporting is provided by averaging results from each frame. The feature allows manual adjustment of software results.	Similar to predicate device. The difference between the subject device and the predicate device is the addition of the lung view quality and pleural line features. The principles of operation for the two added features, including live frame-level display and cineloop-level reporting, remain unchanged compared to the predicate device. The core system software architecture remains unchanged.
Users	Lumify Ultrasound System is used by healthcare professionals.	Lumify Ultrasound System is used by healthcare professionals.	Remains unchanged
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.	Remains unchanged
Transducers	S4-1 C5-2 L12-4	S4-1 C5-2 L12-4	Remains unchanged
Patient Contact Materials	Not applicable. Transducers previously cleared.	Not applicable. Transducers previously cleared.	Remains unchanged
Primary Product Code	IYN	IYN	Remains unchanged
Secondary Product Code	IYO, ITX, QIH	IYO, ITX, QIH	Remains unchanged

7. Safety Considerations

The proposed Lumify Diagnostic Ultrasound System with software function Lung Application 3 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 Lung Application 3 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 Lung Application 3 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 Lung Application 3, 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 two artificial intelligence algorithms integrated into the Philips Lumify Diagnostic Ultrasound System for automated classification of lung view quality and pleural line appearance during clinical LUS examinations.

The primary endpoints evaluated algorithm agreement with ground truth labels for binary classification of (1) Adequate versus Poor lung view quality, and (2) Normal versus Irregular pleural line appearance. The predefined acceptance criterion for each endpoint required the one-sided 97.5% lower confidence limit for the prevalence-adjusted bias-adjusted kappa (PABAK) statistic to exceed 0.35, indicating at least fair agreement with ground truth. The acceptance criteria were established based on published inter-rater agreement ranges for lung view quality and pleural line irregularity among qualified clinical experts.

The Lung View Quality algorithm demonstrated substantial agreement with ground truth for binary classification of Adequate vs. Poor views, achieving 87.9% concordance, Cohen's kappa of 0.67 (95% CI: 0.61–0.72), and PABAK of 0.76 (95% CI: 0.72–0.80). Binary classification performance met the predefined acceptance criterion and was consistent across transducer types (kappa: curved 0.69, sector 0.64, linear 0.65; PABAK: curved 0.76, sector 0.75, linear 0.77). For three-level classification, where Adequate view quality was subcategorized as Good or Limited, the algorithm achieved 71.2% concordance and kappa of 0.64 (95% CI: 0.61–0.68). Algorithm sensitivity and specificity results further support these findings.
The Pleural Line algorithm showed substantial agreement with ground truth for binary classification of Normal versus Irregular pleural line, achieving 85.6% concordance, Cohen's kappa of 0.66 (95% CI: 0.61–0.71), and PABAK of 0.71 (95% CI: 0.67–0.76). The algorithm met the predefined acceptance criterion and was consistent across transducers (kappa: curved 0.68, sector 0.65, linear 0.64; PABAK: curved 0.72, sector 0.70, linear 0.71). For three-level classification, where Irregular pleural line was

subcategorized as Irregular 1 (“definite irregularity”) or Irregular 2 (“pronounced irregularity”), a concordance of 78.4% and kappa of 0.60 (95% CI: 0.56–0.64) was observed. Sensitivity and specificity results further support these findings.

9. Clinical Performance Data

There was no clinical investigation needed for this submission. A study using previously collected clinical ultrasound images with prospective reads by clinicians was conducted to evaluate the performance of the subject device in a simulated clinical setting. The clinical bench study demonstrates the safety and efficacy of the software function Lung Application 3 and confirms the device met the clinical user needs as intended. Substantial equivalence was demonstrated based on the following attributes:

- Design features
- Indications for use
- Fundamental scientific technology
- Non-clinical performance testing
- Safety and Effectiveness

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, Lumify Diagnostic Ultrasound System, including Lung Application 3 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 predicate device (K223771) in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.