May 4, 2023

Philips Ultrasound
% Sudipta Chakrabarti
Sr. Regulatory Affairs Specialist
22100 Bothell Everett Hwy.
BOTHELL WA 98021

Re: K223771
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: March 30, 2023
Received: March 30, 2023

Dear Sudipta Chakrabarti:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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
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and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K223771

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 (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.

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.

510(k) Number: K223771

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

Manufacturer: Philips Ultrasound
22100 Bothell Everett Hwy
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Contact Person: Sudipta Chakrabarti
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Date Prepared: May 1, 2023

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 Name	21 CFR §	Product Code
Primary		
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
Secondary		
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
Transducer, ultrasonic, diagnostic	892.1570	ITX
Automated Radiological Image Processing Software	892.2050	QIH

Device Class: Class II

Classification Panel: Radiology

3. Indications for Use and Intended Use

There is no change to the intended use and indications for use of the subject device as compared to the predicates.

3.1 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.

3.2 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.

4. 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 (2D), Pulsed Wave Doppler, Color Doppler, Combined (B+ Color), and M modes. It is intended to be used by trained professionals at various settings of patient point of care such as clinical admission, periodic evaluations, and prior to hospitalization discharge.

The Lumify system is compatible with iOS or Android operating systems. The B-lines feature is compatible only with Android operating systems and utilizes:

- A commercial off-the-shelf (COTS) Android mobile device (smart phone or tablet)
- The Philips Ultrasound Lumify software running as an application on the COTS device
- The Philips C5-2 Curved array USB transducer
- The Philips L12-4 Linear array USB transducer
- The Philips S4-1 Sector array USB transducer
- Lumify Micro B Transducer Cable
- Lumify Micro C Transducer Cable

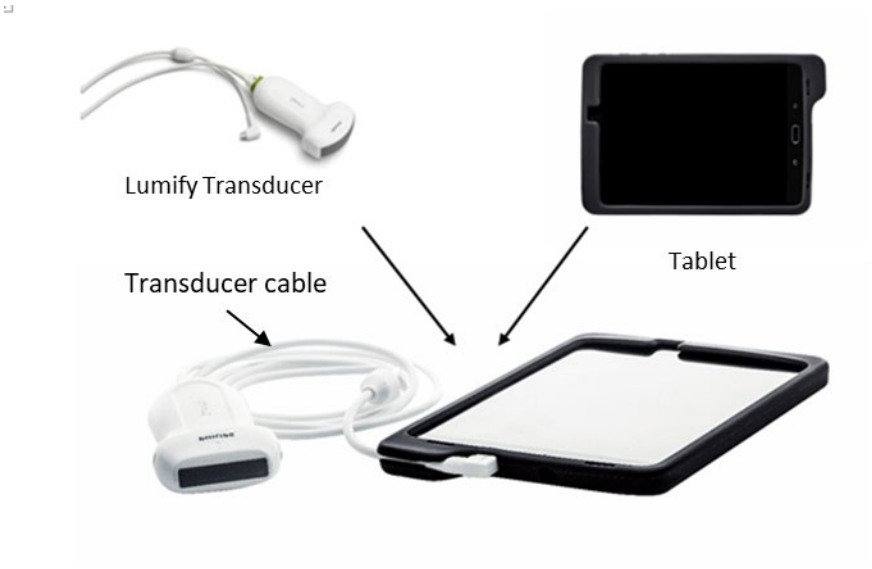

Figure 4-1: Hardware components of Lumify Diagnostic Ultrasound System.

The Lumify system software provides various imaging features, including an Android-specific feature with a guided scan protocol for comprehensive exams and real-time automated B-line assessment during lung exams. B-lines occur when sound waves encounter a mixture of air and water. They are hyperechoic imaging artifacts that appear in a lung exam as long bands of varying widths that originate at the pleural line and extend vertically the length of the ultrasound image. Often, when many B-lines are present and close together, they can merge together and become hard to distinguish from one another and difficult to count accurately. The observation of multiple B-lines merging together is referred to as "merged B-lines" (or otherwise as confluent B-lines, coalescent B-lines, or "white lung" pattern); this can occur as more fluid builds up in the lungs and it becomes increasingly difficult to differentiate between multiple singular B-lines.

The automated B-lines feature is only available in the Lung Preset (which is a specific setting the user selects for ultrasound scanning of the lung) for devices utilizing an Android operating system. The automated B-lines feature also provides a summary page for users to review the highlighted B-lines. The device is a sonographic tool used for assessment of lung involvements in conditions, such as pneumonia, pulmonary edema, lung contusion, and acute respiratory distress syndrome (ARDS) along with clinical and radiological information.

When compared to the predicate device, the subject device has the same software features, but with the addition of an expanded algorithm which includes the detection of merged (confluent) B-lines in the cine loop. In the same manner as the original B-line counting algorithm, the expanded algorithm analyzes lung ultrasound cine video clips (cine loops) acquired using the Lumify Diagnostic Ultrasound System and provides the user the number of B-lines in the loop. The capability of the existing automated B-lines feature (K203406) has been extended to include detection of the presence of merged B-line in cine loops (subject of this submission) and to include support of the expanded B-lines feature (including B-line counting) on a previously cleared Lumify C5-2 transducer (K152899). This software enhancement does not alter the intended use of the device but provides additional functionality to clinical workflows during lung related applications. The Lumify L12-4 and S4-1 transducers were cleared for use with the B-line counting feature via K203406.

The Expanded B-lines Software Feature, with the updated merged B-line detection feature, uses machine learning as part of the algorithm design. Relevant image features extracted from a lung ultrasound cine loop are provided to a machine learning classifier that identifies B-lines and/or merged B-lines in each frame. While the user is scanning the patient during the ultrasound exam, the software automatically counts the number of B-lines in each frame of the loop and determines whether B-lines are considered to be merged. Identified B-lines and merged B-lines in each frame throughout the loop are highlighted.

After the cine loop is acquired, the software determines whether the loop is considered positive for merged B-line. If so, the software reports an output category "⊥" (merged B-line) for that loop. Otherwise, if not merged, the software determines the maximum B-line count within the loop, reported as one of three output categories, "0 B-lines", "1-2 B-lines", or "3+ B-lines". In this way, the subject device informs the user of the presence of merged B-lines in the cine loop, where a B-line count may no longer be an appropriate measurement for that loop. The user can review the highlighted B-lines and merged B-lines and can accept or adjust the reported cine loop output category (0, 1-2, 3+, or ⊥) provided by the software in cases where he or she disagrees with the algorithm output (B-line count or presence of merging). The approved result is then saved for reporting. The software can record the results for up to 12 lung zones (8 anterior zones and 4 posterior zones).

The Philips Lumify Diagnostic Ultrasound System highlights merged B-lines in the frames of a cine loop through depiction of a rendered drawing of a bold inverted T (⊥). The software leverages the Lumify application for image acquisition, visualization, and reporting. The algorithm, that used artificial intelligence/machine learning in its development, is locked (meaning no further adjustments by the algorithm are made and it does not continue to learn once commercialized).

The B-lines algorithm update has no impact on the design, workflow, or intended users of the predicate. This software enhancement does not alter the intended use of the device but provides additional functionality to clinical workflows during lung related applications.

5. Substantially Equivalent Devices

Predicate Device:	K203406 – Philips Ultrasound – Lumify Diagnostic Ultrasound System
Reference Device:	K152899 – Philips Ultrasound – Lumify Diagnostic Ultrasound System, C5-2 transducer

6. Technological Comparison to Predicate Devices

The Lumify Diagnostic Ultrasound System with Merged B-line Counting feature and associated Lumify C5-2 transducer (subject devices) are substantially equivalent to the currently marketed predicate devices (K203406 and K152899, respectively).

The following Table 6.1 provides an overview of the comparison between the subject devices and the currently marketed predicates.

Standard Feature	Lumify Diagnostic Ultrasound System K223771 (Subject Device)	Lumify Diagnostic Ultrasound System K2030406 (Predicate Device)
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging
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.
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. Lumify 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. Lumify 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
Transducers	L12-4 S4-1 C5-2	L12-4 S4-1
Primary Product Code	IYN	IYN
Secondary Product Code	IYO, ITX, QIH	IYO, ITX
Principles of Operation (subject merged B-lines Feature)	Automatic counting of B-lines and detection of merged B-lines, with optional manual adjustment of results provided by the software.	Automatic counting of B-lines, with optional manual adjustment of results provided by the software.

Table 6.1 Technological Comparison of Proposed Subject Device & Predicate Device.

7. Non-Clinical Performance Data

The proposed modification of the Lumify Diagnostic Ultrasound System was tested in accordance with Philips internal procedures. Philips Ultrasound tested the subject device per the following standards to ensure the continued safe and effective performance:

- IEC 62304 Medical device software - Software life cycle processes, 2006 + A 2015
- IEC62366-1 Medical devices – Part 1: Application of usability engineering to medical devices, 2015
- ISO 14971 Medical devices- Application of risk management to medical devices, 2019

Non-clinical verification testing was conducted to address the change and performance test data was provided to support the introduction of the subject software algorithm for the merged B-lines feature. The activities to assure the safe and effective performance of the software revision included, but are not limited to, the following:

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

Non-Clinical Verification Testing of requirements, consisted of feature-specific functional testing, transducer compatibility, user interface and workflow testing related to new functionality introduced in B-Lines for this submission as part of the software verification activities for the system and for each transducer supporting the B-lines feature.

Since this is a software only change and no new hardware was added, no acoustic output, cleaning and disinfectant, thermal, electrical, electromagnetic and mechanical safety testing were required. Biocompatibility testing is not needed for the subject Lumify Ultrasound System with Automated B-Line Counting. The transducer patient contact materials and manufacturing processes are not impacted by the release of the subject Lumify Diagnostic Ultrasound System with automated B-line counting.

8. Clinical Performance Data

Summary of Clinical Tests
There was no clinical investigation needed for this premarket submission of the Lumify Diagnostic Ultrasound System with Expanded B-lines software feature, which is an artificial intelligence-based feature.

Artificial Intelligence Summary
A study using previously collected clinical ultrasound images with prospective reads by clinicians was conducted to evaluate the performance (including merged B-lines and B-line counting). The data used for clinical performance study were completely distinct from that used during training of the algorithm, and there was no overlap between the two data sets.

Dataset
A study involving review by clinicians of 416 LUS (lung ultrasound) video loops were collected from 157 subjects presenting with shortness of breath in a hospital setting. Each subject may have contributed up to 4 video loops. The study data were collected to ensure full coverage of lung, both posterior and interior as well as left and right lungs. The dataset was representative of videos collected from three different transducers.

The demographic distribution of the performance testing includes the following:

Gender	Male and Female
Age	18 to> 89
Ethnicity	Hispanic or Latino and Not Hispanic or Latino

A pre-defined success criteria for the study was assessed as Artificial Intelligence (AI) agreement to the clinicians (ground truth: majority agreement). The agreement target was determined through pilot study conducted to assess clinician's agreement and determined to be based on lower confidence limits of 0.746 for both sensitivity and specificity.

The algorithm performance was verified in sub-groups:

- Transducer: C5-2, L12-4, S4-1

- BMI: <30,>=30,>=40
- Image quality: Poor or Good

Results
Algorithm performance for merged B-line detection and B-line counting was compared to clinician readings.

For merged B-line detection, the sensitivity, specificity, and accuracy (where confidence interval is abbreviated as CI) were as follows:

Transducer	Sample size (video loops)	Sensitivity (95% CI)	Specificity (95% CI)
All	416	0.83 (0.77, 0.88)	0.92 (0.88, 0.96)
C5-2	146	0.89 (0.79, 0.95)	0.96 (0.89, 0.99)
S4-1	150	0.81 (0.72, 0.88)	0.92 (0.80, 0.98)
L12-4	120	0.74 (0.57, 0.88)	0.89 (0.81, 0.95)

For B-line counting, the intraclass correlation coefficient (ICC) for maximum B-line count was as follows:

Transducer	Sample size (video loops)	ICC (95% CI)
All	416	0.91 (0.89, 0.93)
C5-2	146	0.94 (0.91, 0.95)
S4-1	150	0.87 (0.82, 0.90)
L12-4	120	0.91 (0.88, 0.94)

Conclusion
The study demonstrates the safety and efficacy of the Expanded B-Lines Software Feature and confirms the device met the clinical user needs as intended.

9. Sterilization

Not applicable. The ultrasound transducers are not supplied sterile.

10. 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 predicate device (K203406) in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.