Philips Ultrasound, Inc.
% Mr. Colin Jacob
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL WA 98021

February 23, 2021

Re: K203406
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
Dated: January 15, 2021
Received: January 19, 2021

Dear Mr. Jacob:

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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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.

510(k) Number *(if known)*

K203406

Device Name

Lumify Diagnostic Ultrasound System

Indications for Use *(Describe)*

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

Lumify 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.

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510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.
Date Prepared: February 16, 2021

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Colin S. Jacob Senior Regulatory Affairs Specialist TEL: +1 (425)-908-1209 EMAIL: colin.jacob@philips.com
Secondary Contact Information	Benny Lam Principal Regulatory Affairs Specialist TEL: +1 (425)-215-3496 EMAIL: benny.lam@philips.com

II. Device

Trade Name	Lumify Diagnostic Ultrasound System
Common Name	Diagnostic ultrasound system and transducers
Regulation Description	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer
Regulation Number	892.1550 892.1560 892.1570
Primary Product Code	IYN
Secondary Product Codes	IYO ITX
Device Class	Class II
Classification Panel	Radiology

III. Predicate Device

K192226 – Philips Ultrasound – Lumify Diagnostic Ultrasound System

IV. Device Description

Lumify Diagnostic Ultrasound System is a mobile, general, software-control medical device, which is intended to acquire high-resolution ultrasound data and to display the data in various modes of operation. It is intended to be used by trained professionals at various clinical settings including point-of-care.

The Lumify Diagnostic Ultrasound System provides various imaging features including guided scan protocol for comprehensive lung exam. The introduction of the subject B-lines Feature enables the automated detection and counting of B-lines during a lung exam; the subject feature also provides the users the capabilities of reviewing the detected B-lines and editing the number of B-lines for each scanned lung zone.

Clinically, B-line is a lung ultrasound artifact that can aid users in the assessment of patients with a variety of pulmonary conditions and diseases such as pneumonia, pulmonary edema, lung contusion, and acute respiratory distress syndrome (ARDS).

The Lumify Diagnostic Ultrasound System includes:

- A commercial off-the-shelf (COTS) mobile device
- Philips Ultrasound software running as an app on the COTS device
- The C5-2 Curved array USB transducer
- The L12-4 Linear array USB transducer
- The S4-1 Sector array USB transducer
- The Lumify Power Module (LPM) to convert the USB interface used on the family of Lumify transducers to Apple's iAP2 Lightning interface standard used on iPhones and iPads, and to provide battery power to the transducers when using an iOS mobile device.

V. Indications for Use

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

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

VI. Comparison of Technological Characteristics between Proposed Subject Device and Predicate Device

	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Comparison
Regulation Number	892.1550	892.1550	Remains unchanged
Device Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Remains unchanged
Product Code	IYN	IYN	Remains unchanged
Secondary Product Code	IYO, ITX	IYO, ITX	Remains unchanged
Indications for Use	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), 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. Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), 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. Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Added "lung" to indications for use statement
Reusable?	Yes	Yes	Remains unchanged

	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Comparison
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Remains unchanged
Imaging Technology	Ultrasound Imaging	Ultrasound Imaging	Remains unchanged
Principles of Operation (subject B-lines Feature)	Automatic detection and counting of B-lines from lung ultrasound images	Manual counting of B-lines from lung ultrasound images	B-lines Feature is added to the existing Lumify app

VII. Performance Data

The proposed introduction of the Lumify Diagnostic Ultrasound System was tested in accordance with Philips internal processes. Relevant non-clinical testing was conducted to address the change and performance test data is provided to support the introduction of the subject software algorithm for the B-lines Feature. The activities to assure the safe and effective performance of the software revision include but are not limited to the following:

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

VIII. 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 results of the relevant performance data and compatibility support a determination that the proposed subject device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device.