Philips Healthcare
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

September 6, 2019

Re: K192226
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: August 15, 2019
Received: August 16, 2019

Dear Prithul Bom:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192226

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness

Lumify Diagnostic Ultrasound System

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

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

Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact person: Paul Elias, Regulatory Affairs Specialist
Email: Paul.Elias@philips.com
Tel: 425-482-8396
Fax: 425-487-8666
Secondary Contact: Hebe Sun, Senior Regulatory Affairs Manager
Email: Hebe.Sun@philips.com

Date prepared: July 15, 2019

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common name: Diagnostic ultrasound system and transducers
Proprietary name: Lumify Diagnostic Ultrasound System

These devices are classified as follows:

Classification Description	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

As stated in 21 CFR, parts 892.1550, 892.1560, and 892.1570, each of these generic types of devices has been classified as Class II.

3. **Substantially Equivalent Devices**

Philips Ultrasound believes the proposed Lumify Diagnostic Ultrasound System is substantially equivalent to the following currently marketed predicate device:

Predicate Device	510(k)
Lumify Ultrasound System	K162549

4. Device Description

The Lumify Diagnostic Ultrasound System is a mobile, general purpose, software-controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data in various modes of operation. Lumify is a portable system facilitating point of care ultrasound applications.

The Lumify Diagnostic Ultrasound System includes:

- A commercial off-the-shelf (COTS) Android or iOS mobile device
- Philips Ultrasound software running as an app (Android or iOS) 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

5. 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.

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

6. Technological Comparison to Predicate Devices

The Lumify Diagnostic Ultrasound System employs the same fundamental scientific technology as the currently marketed predicate Lumify Ultrasound System (K162549). The transducers, scanning modes, and indications for use are identical. The primary differences are the implementation of the Lumify software application for iOS and the addition of the Lumify Power Module (LPM). The LPM converts the USB interface used on the family of Lumify transducers to Apple's iAP2 Lightning interface, and powers transducers when using an iOS mobile device.

7. Safety Considerations and Nonclinical Performance Testing

As a Track 3 ultrasound device, the Philips Lumify Diagnostic Ultrasound System is designed to comply with the acoustic output display requirements of IEC 60601-2-37 Ed 2.1 (Particular requirements for the basic safety and essential performance of ultrasonic medical and monitoring equipment). The Lumify Diagnostic Ultrasound System complies with the referenced standard as well as the FDA ultrasound guidance document,

"Marketing Clearance of Diagnostic Ultrasound Systems and Transducers," issued on June 27, 2019.

System acoustic output limits are identical to the currently marketed predicate Lumify Ultrasound System (K162549):

- Ispta.3 ≤ 720 MW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

To ensure safety and effectiveness, the Lumify Diagnostic Ultrasound System has been tested to, and is compliant with, the following standards:

- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015

- IEC 60601-1-11:2015: Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment

- IEC 60601-1-12:2015: Medical Electrical Equipment Part 1-12: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014

- AAMI ANSI ISO 10993-1:2009/(R)2013 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process

Quality assurance measures applied to the system design and development included risk analysis, product specifications, design reviews, and verification testing.

Test results supported a determination of substantial equivalence to the predicate device and demonstrated that the Lumify Diagnostic Ultrasound System:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA ultrasound guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

8. Clinical Data

The Lumify Diagnostic Ultrasound System did not require clinical studies because substantial equivalence to the currently marketed predicate Lumify Ultrasound System (K162549) has been established.

9. Conclusion

The hardware and software components enabling the Lumify Diagnostic Ultrasound System expansion from Android to support iOS mobile devices have been successfully verified. The differences between the Lumify Diagnostic Ultrasound System and the predicate Lumify Ultrasound System (K162549) do not raise new questions of safety and/or effectiveness. With identical transducers, scanning modes, and indications for use, the Lumify Diagnostic Ultrasound System is substantially equivalent to the currently marketed predicate Lumify Ultrasound System (K162549).

514 Performance Standards

There are no Sec. 514 performance standards for the Lumify Diagnostic Ultrasound System.

Prescription Status

The Lumify Diagnostic Ultrasound System is a prescription device. The prescription device statement appears in the labeling.

Sterilization Sites

Not applicable. No components are supplied sterile.

Track

The Lumify Diagnostic Ultrasound System is a Track 3 system.