May 8, 2025

Philips Ultrasound
Sudipta Chakrabarti
Principal Regulatory Affairs Specialist
22100 Bothell Everett Hwy
Bothell, Washington 98021-8431

Re: K242670
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: April 9, 2025
Received: April 16, 2025

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 (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.
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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.

Submission Number *(if known)*

K242670

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, Ophthalmic.

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.

TRADITIONAL 510(k)
Philips Ultrasound
Lumify Diagnostic Ultrasound System with Ocular Preset

510(k) Number: K242670

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: Sudipta Chakrabarti
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Date Prepared: May 06, 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 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

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 (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

The purpose of this Traditional 510(k) pre-market notification is to add Ocular preset to currently commercialized L12-4 transducer available with Lumify Diagnostic Ultrasound System. Addition of Ocular preset will be available under newly added Ophthalmic clinical indication, as part of this 510(k) submission.

The Ocular Preset is an imaging setting to image the eye. It supports 2D (B Mode) and Color Doppler Mode and is available under "Ophthalmic" clinical indication.

The ocular preset is available to download with the Lumify 5.1 software and is available with the previously commercialized L12-4 Lumify transducer.

4. Indications for Use and Intended Use

There is no change to the intended use of the subject device due to this change. Ophthalmic is a newly added clinical indication as part of this change, due to addition of Ocular preset.

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, Ophthalmic.

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): K192226, Philips Ultrasound – Lumify Diagnostic Ultrasound System

Reference Device (system): K162329, CX50 Diagnostic Ultrasound System and Sparq Diagnostic Ultrasound System

6. Technological Comparison to Predicate Devices

The following **Table 6.1** provides an overview of the comparison between the subject device and predicate (Lumify Diagnostic Ultrasound System, K192226**)** and reference (Sparq Diagnostic Ultrasound System, K162329**)** devices.

Feature /Characteristic	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Sparq Diagnostic Ultrasound System K162329 (Reference Device)	Comparison/ Discussion/ Comments
Regulation Number	892.1550	892.1550	892.1550	Remains unchanged
Device Classification Name	Ultrasound pulsed doppler imaging system, Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer	Ultrasound pulsed doppler imaging system, Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer	Ultrasound pulsed doppler imaging system, Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer	Remains unchanged
Device Classification	II	II	II	Remains unchanged
Primary Product Code	IYN	IYN	IYN	Remains unchanged
Secondary Product Codes	IYO, ITX	IYO, ITX	IYO, ITX	Remains unchanged
Indications for Use	The Philips Lumify Diagnostic Ultrasound System is intended for diagnostic	The Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B(2D),	**Ophthalmic** Fetal Abdominal Pediatric Small Organ	Remains unchanged except, addition of Ocular preset expands the Lumify Diagnostic

Feature /Characteristic	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Sparq Diagnostic Ultrasound System K162329 (Reference Device)	Comparison/ Discussion/ Comments
	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, **Ophthalmic** The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	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 The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	Adult Cephalic Trans-vaginal Trans-rectal Musculo-skeletal Gynecological Cardiac Adult Trans-Esoph. (Cardiac) Peripheral Vessel	Ultrasound System's indications to include "Ophthalmic". The proposed "Ophthalmic" clinical indication is supported by the reference Sparq Diagnostic Ultrasound System (K162329)
Transducer Clinical Application	L12-4 (subject device with Lumify Diagnostic Ultrasound System) Peripheral Vessel, Carotid, Small Organ, Musculo-skeletal (superficial), Musculo-skeletal (conventional), Lung, Pediatric,	L12-4 (Predicate transducer currently cleared with Lumify Diagnostic Ultrasound System) Peripheral Vessel, Carotid, Small Organ, Musculo-skeletal (superficial), Musculo-skeletal (conventional), Lung, Pediatric, Abdominal	L12-4 (Reference Transducer, currently cleared on the Sparq Diagnostic Ultrasound System) Abdominal, Cardiac Adult, Musculoskeletal (conventional), Musculoskeletal (superficial), **Ophthalmic**, Peripheral Vessel,	Ophthalmic is newly added clinical indication The proposed "Ophthalmic" clinical indication is supported by the reference L12-4 with Sparq Diagnostic Ultrasound System (K162329)

Feature /Characteristic	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Sparq Diagnostic Ultrasound System K162329 (Reference Device)	Comparison/ Discussion/ Comments
	Abdominal, **Ophthalmic**		Small Organ (thyroid, scrotum, prostate, breast)	
Transducer Preset	Lung, MSK, Soft Tissue, Superficial, Vascular, **Ocular**	Lung, MSK, Soft Tissue, Superficial, Vascular	Nerve, Lung, Ocular, MSK, Vascular, Superficial	Ocular is a newly added preset compared to predicate device, L12-4 with Lumify Diagnostic Ultrasound System.
Users	Lumify Ultrasound System is used by healthcare professionals	Lumify Ultrasound System is used by healthcare professionals	Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product.	Remains unchanged from predicate device and similar to reference device
Use 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.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Remains unchanged from the predicate device and similar to reference device

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

7. Safety Considerations

The proposed Lumify Diagnostic Ultrasound System with Ocular preset 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

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 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 Ocular preset included, but are not limited to, the following:

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

9. Clinical Performance Data

The proposed Lumify Diagnostic Ultrasound System with Ocular preset did not require clinical data for determination of substantial equivalence since 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 transducer 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 Ocular preset meets its intended use.

The proposed Lumify Diagnostic Ultrasound System introduces Ophthalmic as a new clinical indication compared to predicate Lumify Diagnostic Ultrasound System (K192226), due to addition of Ocular preset. Ocular preset will only be available on previously cleared L12-4 transducer. Ophthalmic clinical indication is previously cleared with Reference system, Sparq Diagnostic Ultrasound System, K162329.

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 proposed device is substantially equivalent to the predicate and reference devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.