Philips Ultrasound
℅ Sudipta Chakrabarti
Sr. Regulatory Affairs Specialist
22100 Bothell Everett Hwy
BOTHELL WA 98021-8431

October 26, 2023

Re: K232500
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: August 17, 2023
Received: August 17, 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 (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.

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
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232500

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.

TRADITIONAL 510(k) SUMMARY
Philips Ultrasound
Lumify Diagnostic Ultrasound System with Auto EF Quantification

510(k) Number: K232500

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
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Contact Person: Sudipta Chakrabarti
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Date Prepared: October 26, 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		
Ultrasonic pulsed doppler imaging system	892.1550	IYN
Secondary		
Ultrasonic pulsed echo imaging system	892.1560	IYO
Diagnostic ultrasonic transducer	892.1570	ITX
Medical image management and processing system	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 currently commercialized version of Lumify Diagnostic Ultrasound System, except lung indication was added through K203406 for Lumify Diagnostic Ultrasound System with B-line Detection and B-line Counting, and Pulsed Wave Doppler was added during Lumify 4.0 (Android) release through a Letter to File.

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.

The Lumify Diagnostic Ultrasound System (Android) 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 is compatible with iOS or Android operating systems. The Lumify system software provides various imaging features, including an Android-specific feature with artificial intelligence (AI) based, Auto EF Quantification (ejection fraction) technology during cardiac imaging. Ejection fraction (EF) is a measurement, expressed as a percentage, of how much blood the left ventricle pumps out with each contraction of the heart. The End Diastolic Volume (EDV) and the End Systolic Volume (ESV) are the volumes used to calculate the blood ejected from the left ventricle per heartbeat.

Auto EF is a new Artificial Intelligence (AI) feature available on the S4-1 transducer in the Cardiac Preset on the Lumify application based on the LVivo EF algorithm developed by DiA. Lumify Auto EF Quantification feature is a subset of LVivo platform. It provides automated assessment of the LV EF supporting evaluation from only apical four chamber (A4CH) view. The software automatically traces and tracks LV borders in each frame of the cardiac cycle and provides only the results for Ejection Fraction (EF), End Diastolic Volume (EDV), and End Systolic Volumes (ESV). Auto EF only includes a mechanism for automatically rejecting false results. If the algorithm fails to compute the results, then the user is notified by displaying an error dialog. Additionally, the tool offers editing functionality to review and adjust the LV contour before accepting it for calculating the results. The Auto EF Quantification feature will be available on version 5.0 (Android) of Lumify Diagnostic Ultrasound System.

The Auto EF Quantification has no impact on the clinical indication 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 cardiac related applications.

5. Substantially Equivalent Devices

Predicate Device: K162549, Philips Ultrasound – Lumify Diagnostic Ultrasound System

Reference Device: K210053, DiA LVivo Software Application

Additional Reference Devices K223771, Philips Ultrasound – Lumify Diagnostic Ultrasound System
K203406, Philips Ultrasound – Lumify Diagnostic Ultrasound System

6. Technological Comparison to Predicate Devices

The Lumify Diagnostic Ultrasound System with Auto EF Quantification and associated transducers are substantially equivalent to the predicate device (K162546) and reference device (K210053).

The following **Table 6.1** provides an overview of the comparison between the subject devices and predicate and reference devices.

Standard Feature	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K162549 (Predicate Device)	DiA LVivo Software Application K210053 (Reference Device)	Comparison/ Discussion
Regulation Number	892.1550	892.1550	892.2050	Remains unchanged from predicate Lumify Ultrasound System
Device Classification Name	System, Imaging, Pulsed Doppler, Ultrasonic	System, Imaging, Pulsed Doppler, Ultrasonic	Automated Radiological Imaging Processing Software	Remains unchanged
Device Classification	II	II	II	Remains unchanged
Primary Product Code	IYN	IYN	QIH	Remains unchanged from predicate Lumify Ultrasound System QIH is a secondary product for subject device
Feature Trade Name	Auto EF Quantification	Not Applicable This feature was not available with this version	LVivo EF	LVivo software application has been incorporated in Lumify Ultrasound System as Auto EF Quantification
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Relies on Ultrasound imaging to perform the assessment	Remains unchanged for the predicate and similar for the reference
Principles of Operation (subject Auto EF Quantification Feature)	Lumify Auto EF Quantification is a software only feature. The core system software architecture remains unchanged. This	Not Applicable This feature was not available with this version	The LVivo platform is a software system for automated analysis of ultrasound examinations.	With Auto EF Quantification feature the user is offered an automated measurement of Ejection Fraction (EF), End Diastolic Volume (EDV), and

Standard Feature	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K162549 (Predicate Device)	DiA LVivo Software Application K210053 (Reference Device)	Comparison/ Discussion
	additional feature is added in the Cardiac preset of the Lumify system to assess left ventricular function using a 4 Chamber Apical view of the heart. This feature provides automated tracing of the Left Ventricular (LV) border and quantification of End Systolic Volume (ESV) and End Diastolic Volumes (EDV) as well as the Ejection Fraction (EF) for LV assessment.			End Systolic Volume (ESV). The Lumify features are a subset of the LVivo platform
Artificial Intelligence/Machine Learning	Auto EF Quantification, is a derivative of the previously cleared LVivoEF module (K210053) that enables automated evaluation of end diastolic volume (EDV), end systolic volume (ESV) and Ejection Fraction (EF) from the Four Chamber (4CH) apical view.	Not Applicable This feature was not available with this version	Automated analysis of echocardiographic examinations is done based on ultrasound imaging data by analyzing already acquired clip (cine loop). The imaging data can be provided in DICOM format that includes required metadata or RGB format together with metadata that is provided through software API. The global LV function is evaluated from two of the apical views: four-chamber (4CH) and	The subject device with the automation of the Auto EF Quantification feature, the user is now offered measurements including Ejection Fraction (EF), End Diastolic Volume (EDV) and End Systolic Volume (ESV). The AL/ML functionality is same in the subject device in comparison to the reference device.

Standard Feature	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K162549 (Predicate Device)	DiA LVivo Software Application K210053 (Reference Device)	Comparison/ Discussion
			two-chamber (2CH) by calculating ejection fraction (EF). The LVivo EF supports global LV function evaluation from single view or Biplane"	
Automation	Yes	Not Applicable This feature was not available with this version	Yes	Same as the reference device (DiA LVivo)
Manual editing by user capability	Yes	Not Applicable This feature was not available with this version	Yes	Same as the reference device (DiA LVivo)
Automated ED and ES frames selection	Yes	Not Applicable This feature was not available with this version	Yes	Same as the reference device (DiA LVivo)
Volume calculation by Simson's method of discs	Yes	Not Applicable This feature was not available with this version	Yes	Same as the reference device (DiA LVivo)
EF results presentation	Displaying full clip with border tracking. The results for selected ED and ES frames for default beat is displayed.	Not Applicable This feature was not available with this version	Displaying full clip with border tracking. And table with results for each cycle for selected ED & ES frames for each beat.	Auto EF for Lumify does not have the table with results for each cycle. Only results for ED & ES frames for default beat is displayed.
Algorithm	Image segmentation for border detection and tracking includes processing by neural network	Not Applicable This feature was not available with this version .	Image segmentation for border detection and tracking includes processing by neural network	Same as reference device

Standard Feature	Lumify Diagnostic Ultrasound System K# Pending (Subject Device)	Lumify Diagnostic Ultrasound System K162549 (Predicate Device)	DiA LVivo Software Application K210053 (Reference Device)	Comparison/ Discussion
Automated rejection of false results	Yes	Not Applicable This feature was not available with this version	Yes	Same as the reference device (DiA LVivo)
Transducers	L12-4 S4-1 C5-2 Auto EF is only available on S4-1 Transducer (Cardiac Phased Array)	L12-4 S4-1 C5-2	Cardiac Phased Array	Auto EF Quantification feature is only available on S4-1 transducer

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 were provided to support the introduction of the subject software algorithm for the Auto EF software 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 Review
- Product Specification Review
- Design Reviews

Non-Clinical Verification Testing of requirements, consisted of feature-specific functional testing, transducer compatibility, user interface and workflow testing related to Auto EF Software Feature introduced in this submission as part of the software verification activities for the system and for S4-1 transducer supporting the Auto EF Software 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 Auto EF Quantification. The transducer patient contact materials and manufacturing processes are not

impacted by the release of the subject Lumify Diagnostic Ultrasound System with Auto EF Quantification.

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 Auto EF Quantification feature, which is an artificial intelligence-based feature. The LVivo EF was developed by DiA Imaging Analysis Ltd. and integrated into Lumify Diagnostic Ultrasound device as Auto EF Quantification.

Artificial Intelligence Summary

The LVivo EF algorithm is an Artificial Intelligence (AI) based tool that enables automated assessment of the global LV function.

A clinical performance study using Apical 4 Chamber (A4CH) view clips from 80 patients acquired with the Lumify Diagnostic Ultrasound System, compared the automated EF evaluation by LVivo EF to Ejection Fraction (EF) evaluation by manual tracing performed by sonographers. 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

The data set consisted of Apical 4CH view clips obtained from 80 subjects who were referred for cardiac evaluation. These subjects were selected based on their eligibility for study.

The data were acquired consecutively for patients with normal LV function and then for patients with impaired LV function. For each patient, a scan of the 4CH apical view was performed using Lumify Diagnostic Ultrasound System when EF by visual estimation on the Lumify device was possible.

The examinations were identified by patient number and collected anonymized.

The demographic distribution of the study population includes the following:

Variables	Values	N	%	Mean
Gender	Female	23	29	--
	Male	57	71	--
Age	19 - 92 years	80	--	64 ± 14 years
BMI	15.9-43.0	74*	--	26.4
LV Function	Normal or preserved LV function	30	37.5	--
	Mild LV dysfunction	13	16.25	--
	Moderate LV dysfunction	20	25	--
	Severe LV dysfunction	17	21.25	--
Population disease distribution	Coronary artery disease (CAD)	34	42	--
	Left Ventricular Hypertrophy	9	11	--
	Thickened leaflet, Calcified or prosthetic mitral valve	19	24	--
	Moderate to Severe Mitral regurgitation	7	9	--
	Normal LV Function	11	14	--

*BMI data were not available for 6 patients.

A comparison was conducted between the automated EF results obtained by the LVivo EF application, and the average Ejection Fraction (EF) results obtained through manual tracing, which is a conventional method for echocardiographic LV function evaluation.

Results

Strong correlation was demonstrated between LVivo EF ejection fraction (EF) measurements and the average results by manual tracing, r=0.82, 95% CI (0.72, 0.88), meeting the end point criteria. Additionally, strong correlations were demonstrated for end-diastolic volume (EDV) and end-systolic volume (ESV) with r=0.95, 95% CI (0.91, 0.96) and r= 0.94, 95% CI (0.90, 0.96), respectively.

The LVivoEF automatically processed 76 out of 80 clips (95%). The automated results were compared to EF results by manual tracing.

Conclusion

Auto EF application accurately measured LV function when applied to 4CH clips collected with the Lumify Diagnostic Ultrasound Device. The Auto EF application can be used as an analysis tool for EF evaluation on clips acquired with the Lumify device.

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 primary predicate device in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.