May 15, 2025

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

Re: K242519
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 23, 2024
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.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242519

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, Trans-vaginal.

The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by appropriately trained 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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TRADITIONAL 510(k) Summary
Philips Ultrasound
Lumify Diagnostic Ultrasound System with C9-4ec

510(k) Number: K242519

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
Principal Regulatory Affairs Specialist
sudipta.chakrabarti@philips.com

Phone: 615-243-8084

Secondary Contact: Amy Yang
Director Regulatory Affairs
amy.yang@philips.com

Date Prepared: May 13, 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		
Ultrasonic pulsed doppler imaging system	892.1550	IYN
Secondary		
Ultrasonic pulsed echo imaging system	892.1560	IYO
Diagnostic ultrasonic transducer	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. The Philips C9-4ec Curved linear array USB Transducer (subject of this submission)
7. Lumify Micro B Transducer Cable
8. Lumify Micro C Transducer Cable
9. Lumify USB-C to USB-C Transducer Cable
10. Lumify Power Module (LPM)
11. Lumify USB-C to Lightning LPM Cable

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

The purpose of this traditional 510(k) submission is addition of C9-4ec Transducer and Fertility Package to Lumify Diagnostic Ultrasound System.

The C9-4ec transducer is an Endo-cavitary (intravaginal) curved linear probe designed for obstetrical, gynecological and fertility application. C9-4ec transducer is indicated for the following clinical applications: Gynecological (previously cleared), Fetal/Obstetric (previously cleared), and Trans-vaginal (newly added as part of this 510(k) submission). The C9-4ec transducer is compatible with the Lumify iOS 5.1 version and will be added to Lumify Android 5.1 in the future.
The Fertility Package will allow a user to perform the required labeled measurements for the endometrial thickness and a two-distance measurement as well as the Mean/Average Diameter derived calculation of up to 15 follicles within each ovary. In addition, it will provide users a Summary Page that provides detailed measurements of each follicle as well as measurements of the endometrial thickness.

4. Indications for Use and Intended Use

There is no change to the intended use of the subject device due to this change. Trans-vaginal is a newly added clinical indication as part of this change, due to addition of C9-4ec transducer.

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, Trans-vaginal.

The Lumify system is a transportable ultrasound system intended for use in environments where healthcare is provided by appropriately trained 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:	K192226, Philips Ultrasound – Lumify Diagnostic Ultrasound System
Primary Reference Device:	K120321, C9-4v Transducer with ClearVue Ultrasound System
Secondary Reference Device:	K240850, C9-4v Transducer with Philips Affiniti Series Diagnostic Ultrasound System (system)

6. Technological Comparison to Predicate Devices

The following **Table 6.1** provides an overview of the comparison between the subject device, predicate (Lumify Diagnostic Ultrasound System, K192226**),** primary reference device (C9-4v with ClearVue Ultrasound System, K120321), and secondary reference device (C9-4v with Affiniti Series Diagnostic Ultrasound System, K240850**)** devices.

Feature /Characteristic	**Lumify Diagnostic Ultrasound System K242519 (Subject Device)**	**Lumify Diagnostic Ultrasound System K192226 (Predicate Device)**	**C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)**	**C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)**	**Comparison/Discussion/Comments**
Regulation Number	892.1550	892.1550	892.1550	892.1550	Identical
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	Ultrasound pulsed doppler imaging system, Ultrasonic pulsed echo imaging system, Diagnostic ultrasonic transducer	Identical
Device Classification	II	II	II	II	Identical
Primary Product Code	IYN	IYN	IYN	IYN	Identical to predicate device
Secondary Product Codes	IYO, ITX	IYO, ITX	IYO, ITX	IYO, ITX	Identical to predicate device
Feature Trade Name	Fertility Package	Not applicable This feature was not available with this version	Fertility calculation package	Fertility calculation package	Fertility count feature has been added under the Fertility preset for subject device with the newly added C9-4ec transducer. The Fertility Package is currently available with Affiniti Series Ultrasound System and ClearVue Ultrasound System. The version of

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
					this features will be available with the subject device is an expansion and enhancement of this Fertility measurement feature. Main differences include: The Lumify allows for a two distance diameter measurement vs a single distance diameter measurement offered on Affiniti and ClearVue The Lumify offers a mean diameter based on two distance diameter performed for each follicle vs follicle volume calculated from one diameter distance for each follicle in on Affiniti and ClearVue. The Lumify allows a maximum of up to 15 READILY LABELED follicles to be measured on each side of the ovary while the Affiniti only allows for a maximum of 10 READILY LABELED follicles on each side of the ovary and ClearVue allows 8 READILY LABELED follicles on each side of the ovary.

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
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, **Trans-vaginal** The Lumify system is a transportable ultrasound system intended for use in environments where healthcare	The 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,	Fetal/Obstetric, Abdominal, Pediatric, Small Organ (thyroid, scrotum, prostate, breast), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Gynecological, Cardiac Adult, Cardiac Pediatric, Cardiac Other: Fetal, Peripheral Vessel, Peripheral Vessel Other: Carotid	Abdominal, Cardiac Adult, Cardiac Other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Trans-vaginal, Lung.	Identical to predicate device, except Lung was added through K203406 for Lumify Diagnostic Ultrasound System with B-line Detection and B-line counting feature and Pulsed Wave Doppler (PWD) was added during the Lumify software version 5.0 release through a Letter to File. The letter to file is consistent with FDA guidance document: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers – Guidance for Industry and Food and Drug Administration Staff, February 21, 2023, Section 5.1.2.2, Table 2: Well-established ultrasound modes of operation Trans-vaginal clinical indication is a newly added clinical indication as part of the subject 510(k) submission. "Trans-vaginal" clinical indication is available on reference devices.

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
	is provided by healthcare professionals.	Carotid, Cardiac The Lumify system 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), Color Doppler, Combined (B+Color), and M modes	B (2D), M modes, PWD, CWD, Color Doppler, Combined: B+PWD, B+Color, B+M, B+M+Color, B+Color+PWD, B+CWD, B+Color+CWD	B (2D), M modes, PWD, CWD, Color Doppler, Combined (B+PWD; B+Color; B+Amplitude; B+M), Combined (B+M+Color), Combined (B+Color+PWD ; B+Amplitude+ PWD), Combined (B+CWD; B+Color+CWD; B+Amplitude+ CWD)	Identical to predicate device, except Pulsed Wave Doppler (PWD) was added during the Lumify software version 5.0 released through a Letter to File. The letter to file is consistent with FDA guidance document: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers – Guidance for Industry and Food and Drug Administration Staff, February 21, 2023, Section 5.1.2.2, Table 2: Well-established ultrasound modes of operation. There is no change to the Modes of

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
					Operations due to the addition of new transducer, C9-4ec subject to this 510(k) submission.
Principles of Operation (subject Fertility Count preset)	The primary use of the Fertility preset is to perform a focused gynecological study using 2D, PW, and Color modes. The preset will be used to assess a patient's fertility status by evaluating the endometrium (appearance, size, and presence of pathology), and uterus, ovaries, and adnexa (uterine and ovarian size and appearance, presence of uterine, ovarian, and adnexal pathology, presence/number of antral follicles, and progressive ovarian follicular and endometrial lining growth post hormonal stimulation)	Not Applicable This preset was not available with this version.	The primary use of the Fertility preset is to perform a focused gynecological study using 2D, PW, and Color modes. The preset will be used to assess a patient's fertility status by evaluating the endometrium (appearance, size, and presence of pathology), and uterus, ovaries, and adnexa (uterine and ovarian size and appearance, presence of uterine, ovarian, and adnexal pathology, presence/number of antral follicles, and progressive ovarian follicular and endometrial lining growth post hormonal stimulation)	The primary use of the Fertility preset is to perform a focused gynecological study using 2D, PW, and Color modes. The preset will be used to assess a patient's fertility status by evaluating the endometrium (appearance, size, and presence of pathology), and uterus, ovaries, and adnexa (uterine and ovarian size and appearance, presence of uterine, ovarian, and adnexal pathology, presence/number of antral follicles, and progressive ovarian follicular and endometrial lining growth	Identical to reference devices

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
				post hormonal stimulation)	
Patient Population for Fertility Package	Gynecology patients for follicular assessment	Not applicable. Fertility package is not available in the currently commercialized version of Lumify	Gynecology patients for follicular assessment	Gynecology patients for follicular assessment	Identical to reference devices
Users	Lumify Ultrasound System is used by healthcare professionals	Lumify Ultrasound System is used by healthcare professionals	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product.	Trained healthcare professionals Intended for sonographers, physicians, and biomedical engineers who operate and maintain your product.	Identical to predicate 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.	Clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Identical to predicate device
Compatible Transducers	L12-4 S4-1 C5-2 **C9-4ec**	L12-4 S4-1 C5-2	C9-4v	C9-4v	C9-4ec is a newly added transducer for the subject device in

TRADITIONAL 510(k)
Philips Ultrasound
Lumify Diagnostic Ultrasound System with C9-4ec

Feature /Characteristic	Lumify Diagnostic Ultrasound System K242519 (Subject Device)	Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	C9-4v with ClearVue Ultrasound System K120321 (Primary Reference Device)	C9-4v with Affiniti Series Diagnostic Ultrasound System K240850 (Secondary Reference Device)	Comparison/Discussion/Comments
					comparison to the predicate device.
Transducer Characteristics					
C9-4ec Transducer Model	Endocavitary Curved linear transducer	Not applicable. C9-4ec is not available with this version.	Endocavitary Curved linear transducer	Endocavitary Curved linear transducer	Identical to reference devices. C9-4ec is a newly added transducer as part of this 510(k) submission.
New Transducer Indications for Use	Indications for C9-4ec transducer: Gynecological, Fetal/Obstetric, and Trans-vaginal	Not applicable. C9-4ec is not available with this version.	Indications for C9-4v transducer: Fetal/Obstetric, Trans-Rectal, Trans-vaginal, Gynecological	Fetal/OB, Trans-vaginal, GYN, Urology, Fetal Echo	Identical to primary reference device, except proposed C9-4ec does not have trans-rectal clinical indication.
Transducer preset	C9-4ec: Fertility, Gyn Pelvis, OB Early	Not applicable. C9-4ec is not available with this version.	OB EV Gyn EV Gyn EV Fertility Urology EC Prostate	Gyn Fertility, Gyn Pelvis, Gyn Penetration, OB Early, OB Fetal Heart, OB General, Urology Bladder	Similar to secondary reference device. Secondary reference device has additional presets that are not available on the proposed C9-4ec
C9-4ec Transducer Modes of Operations	Fertility, Gyn Pelvis: B (2D), Color Flow, M-Mode, PW Doppler OB Early: B (2D), Color Flow, M-Mode	Not applicable. C9-4ec is not available with this version	B (2D), M mode, PW Doppler, Color Doppler, Combined: B + PWD; B + Color; B + Amplitude; B + M, Combined: B + M + Color, Combined: B + Color + PWD; B + Amplitude + PWD	B (2D), M mode, PW Doppler, Color Doppler, Combined: B + PWD; B + Color; B + Amplitude; B + M, Combined: B + M + Color, Combined: B + Color + PWD; B + Amplitude + PWD	Similar to reference devices. Reference devices have additional modes available.
510(k) Track	Track 3	Track 3	Track 3	Track 3	Identical

Table 6.1 Technological Comparison of Proposed Subject Device, Predicate Device & Reference Devices

7. Safety Considerations

The proposed Lumify Diagnostic Ultrasound System with C9-4ec transducer, are all Track 3 devices 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
- IEC 60601-1 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-37- Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-1-2 4.1 ed - Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests; 2020
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017-09
- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process; 2018

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 C9-4ec transducer 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 C9-4ec transducer 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 as well as newly added C9-4ec 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 C9-4ec transducer meets its intended use.

The proposed Lumify Diagnostic Ultrasound System introduces Trans-vaginal as a new clinical indication compared to predicate Lumify Diagnostic Ultrasound System (K192226). The addition of Trans-vaginal clinical indication is due to the addition of C9-4ec transducer. Trans-vaginal clinical indication is previously cleared with Reference devices, C9-4v transducer for Affiniti Diagnostic Ultrasound System (K240850) and C9-4v transducer for ClearVue Ultrasound System (K120321).

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