Philips Ultrasound, Inc.
℅ Deep Pal
Director, Regulatory Affairs
22100 Bothell Everett Highway
Bothell WA 98021

May 1, 2020

Re: K201012
Trade/Device Name: Affiniti Diagnostic Ultrasound System Series
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: April 17, 2020
Received: April 20, 2020

Dear Deep Pal:

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)*
K201012

Device Name
Affiniti Diagnostic Ultrasound System Series

Indications for Use *(Describe)*

The intended use of the Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal.

The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgment and best clinical procedure.

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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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)*
K201012

Device Name
CX50 Diagnostic Ultrasound System

Indications for Use *(Describe)*
Philips CX50 Diagnostic Ultrasound Systems is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes.
It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Intraoperative Laparoscopic Fetal Abdominal Pediatric Small Organ Adult Cephalic Neonatal Cephalic Trans-vaginal Musculo-skeletal Gynecological Cardiac Adult Cardiac Pediatric Trans-Esoph. (Cardiac) Intracardiac echo Peripheral Vessel Other (Carotid)

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K201012

Device Name
EPIQ Diagnostic Ultrasound System Series

Indications for Use *(Describe)*
The intended use of the EPIQ, EPIQ 5, EPIQ 7 is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal.
The clinical environments where the EPIQ Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.
When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance.
The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgment and best clinical procedure.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201012

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)

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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)*
K201012

Device Name
QLAB Advanced Quantification Software

Indications for Use *(Describe)*
QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.

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)

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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)*
K201012

Device Name
Sparq Diagnostic Ultrasound System

Indications for Use *(Describe)*
Philips Sparq Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Fetal Abdominal Pediatric Small Organ Adult Cephalic Trans-vaginal Trans-rectal Musculo-skeletal Gynecological Cardiac Adult Trans-Esoph. (Cardiac) Peripheral Vessel.

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)

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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: April 30, 2020

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Deep Pal Head of Regulatory Affairs TEL: +1 (425) 219-3412 EMAIL: deep.pal@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	Philips Lumify Diagnostic Ultrasound System Philips EPIQ Diagnostic Ultrasound System Series Philips Affiniti Diagnostic Ultrasound System Series Philips CX50 Diagnostic Ultrasound System Philips Sparq Diagnostic Ultrasound System Philips QLAB Advanced Quantification Software
Common Name	Diagnostic ultrasound system and transducers Automated Radiological Image Processing Software
Regulation Description	Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasonic transducer Picture archiving and communications system
Regulation Number	892.1550 892.1560 892.1570 892.2050
Product Code	IYN
Secondary Product Codes	IYO

	ITX
	QIH
Device Class	Class II
Classification Panel	Radiology

III. Predicate Device

- K192226 - Philips Lumify Diagnostic Ultrasound System
- K182857 - Philips EPIQ Diagnostic Ultrasound System
- K182857 - Philips Affiniti Diagnostic Ultrasound System
- K162329 - Philips CX50 Diagnostic Ultrasound System
- K162329 - Philips Sparq Diagnostic Ultrasound System
- K191647 - QLAB Advanced Quantification Software

IV. Device Description

Philip Diagnostic Ultrasound Systems are durable, reusable capital equipment medical devices which are intended for high-resolution general imaging, interventional radiology, cardiology, vascular and OB/GYN applications and fluid flow analysis. They are intended to be used by trained professionals at various settings of patient care such as clinical admission, periodic evaluations, prior to hospitalization discharge, and/or academic research, via maneuverable caster wheels or mobile handheld components.

Philips QLAB Advanced Quantification software (QLAB) is designed to view and quantify image data acquired on Philips ultrasound systems. QLAB is available either as a stand-alone product that can function on a standard PC, a dedicated workstation, and on-board Philips' Diagnostic Ultrasound Systems.

Software modes/applications, scanning protocols, and pre-installed settings or functionality to create dedicated settings for imaging of specific anatomy are available with the subject Philips Diagnostic Ultrasound Systems and QLAB software and may vary among model configurations.

The diagnostic ultrasound systems are manufactured with hardware components which consist of:

1) a primary console (e.g., workstation, tablet) with built-in software components, features, and various clinical applications, and
2) a range of compatible ultrasound transducers.

A suite of compatible transducer types are offered such as transesophageal echocardiography (TEE) transducers, non-imaging (pencil) probes, curved array, linear array and sector/phased array. Curved array transducer models which have a prefix "C" are designed to provide larger fields of view and penetration for e.g., consolidation between bone spaces while linear array transducer models, which can be identified with a "L" prefix model name are designed to provide shallow visualization which are optimal for tissue layer interfaces. Sector/phased array transducer models which usually have a "S" prefix model names are designed to be applied for difficult anatomical sites (e.g., cardiac intercostal space (ICS)). Other Philips ultrasound transducers may also start with the prefix "X" which is referring to the xMatrix technology for two full-resolution planes of imaging. Volumetric three-dimensional (3D) imaging functionality is also available when specific transducer models are connected to the primary console. Philips ultrasound

transducers may be bagged into compatible transducer/probe cover sheaths, designed by other manufacturers, for each procedure to prevent cross-contamination and reduce the risk of healthcare-associated infections.

Some configurations may have additional previously-cleared accessories, components and software features which are manufactured by Philips Ultrasound, Inc. or other manufacturers.

V. Indications for Use

Device	Indications for Use
Philips Lumify Diagnostic Ultrasound System	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.
Philips EPIQ Diagnostic Ultrasound System	The intended use of the EPIQ, EPIQ 5, EPIQ 7 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the EPIQ Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure.
Philips Affiniti Diagnostic Ultrasound System	The intended use of the Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance.

Device	Indications for Use
	The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure
Philips CX50 Diagnostic Ultrasound System	Philips CX50 Diagnostic Ultrasound Systems is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Intraoperative Laparoscopic Fetal Abdominal Pediatric Small Organ Adult Cephalic Neonatal Cephalic Trans-vaginal Musculo-skeletal Gynecological Cardiac Adult Cardiac Pediatric Trans-Esoph. (Cardiac) Intracardiac echo Peripheral Vessel Other (Carotid)
Philips Sparq Diagnostic Ultrasound System	Philips Sparq Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Fetal Abdominal Pediatric Small Organ Adult Cephalic Trans-vaginal Trans-rectal Musculo-skeletal Gynecological Cardiac Adult Trans-Esoph. (Cardiac) Peripheral Vessel
QLAB Advanced Quantification software	QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.

VI. Comparison of Technological Characteristics with the Predicate Device

Table 1: Technological Comparison of Subject Device (i.e., Philips Lumify Diagnostic Ultrasound System) & Predicate Device

Standard Feature	Philips Lumify Ultrasound System K# Pending (Subject Device)	Philips Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Comparison
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.	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.	Identical
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	Compatible device generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end.	Compatible device generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end.	Identical

Standard Feature	Philips Lumify Ultrasound System K# Pending (Subject Device)	Philips Lumify Diagnostic Ultrasound System K192226 (Predicate Device)	Comparison
	Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Type of Previously-cleared Transducers	Curved Array Linear Array Sector Array	Curved Array Linear Array Sector Array	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Table 2: Technological Comparison of Subject Device (i.e., Philips EPIQ Diagnostic Ultrasound System Series) & Predicate Device

Standard Feature	Philips EPIQ Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips EPIQ Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
Indications for Use	The intended use of the EPIQ, EPIQ 5, EPIQ 7 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the EPIQ Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of	The intended use of the EPIQ, EPIQ 5, EPIQ 7 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the EPIQ Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of	Identical

Standard Feature	Philips EPIQ Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips EPIQ Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
	cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure.	cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are	Identical

Standard Feature	Philips EPIQ Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips EPIQ Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
	reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Type of Previously-cleared Transducers	Curved Array Linear Array Sector Array	Curved Array Linear Array Sector Array	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Table 3: Technological Comparison of Subject Device (i.e., Philips Affiniti Diagnostic Ultrasound System Series) & Predicate Device

Standard Feature	Philips Affiniti Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips Affiniti Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
Indications for Use	The intended use of the Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with	The intended use of the Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: 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, Transvaginal. The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with	Identical

Standard Feature	Philips Affiniti Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips Affiniti Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
	image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure.	image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance. The systems are intended to be installed, used, and operated only in accordance with the 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 your responsibility for sound clinical judgement and best clinical procedure.	
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus	Identical

Standard Feature	Philips Affiniti Diagnostic Ultrasound System Series K# Pending (Subject Device)	Philips Affiniti Diagnostic Ultrasound System Series K182857 (Predicate Device)	Comparison
	membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Type of Previously-cleared Transducers	Curved Array Linear Array Sector Array	Curved Array Linear Array Sector Array	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Table 4: Technological Comparison of Subject Device (i.e., Philips CX50 Diagnostic Ultrasound System) & Predicate Device

Standard Feature	Philips CX50 Diagnostic Ultrasound System K# Pending (Subject Device)	Philips CX50 Diagnostic Ultrasound System K162329 (Predicate Device)	Comparison
Indications for Use	Philips CX50 Diagnostic Ultrasound Systems is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Intraoperative Laparoscopic Fetal Abdominal Pediatric Small Organ Adult Cephalic Neonatal Cephalic Trans-vaginal Musculo-skeletal Gynecological Cardiac Adult Cardiac Pediatric Trans-Esoph. (Cardiac) Intracardiac echo Peripheral Vessel Other (Carotid)	Philips CX50 Diagnostic Ultrasound Systems is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Intraoperative Laparoscopic Fetal Abdominal Pediatric Small Organ Adult Cephalic Neonatal Cephalic Trans-vaginal Musculo-skeletal Gynecological Cardiac Adult Cardiac Pediatric Trans-Esoph. (Cardiac) Intracardiac echo Peripheral Vessel Other (Carotid)	Identical
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	System console generates electrical current and sends to a connected, compatible transducer to stimulate its	System console generates electrical current and sends to a connected, compatible transducer to stimulate its	Identical

Standard Feature	Philips CX50 Diagnostic Ultrasound System K# Pending (Subject Device)	Philips CX50 Diagnostic Ultrasound System K162329 (Predicate Device)	Comparison
	piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	piezoelectric elements at the distal end. Stimulation causes the elements to expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Type of Previously-cleared Transducers	Curved Array Linear Array Sector Array	Curved Array Linear Array Sector Array	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Table 5: Technological Comparison of Subject Device (i.e., Philips Sparq Diagnostic Ultrasound System) & Predicate Device

Standard Feature	Philips Sparq Diagnostic Ultrasound System K# Pending (Subject Device)	Philips Sparq Diagnostic Ultrasound System K162329 (Predicate Device)	Comparison
Indications for Use	Philips Sparq Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Fetal Abdominal Pediatric Small Organ Adult Cephalic Trans-vaginal Trans-rectal Musculo-skeletal Gynecological Cardiac Adult Trans-Esoph. (Cardiac) Peripheral Vessel	Philips Sparq Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (or 2- D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic Fetal Abdominal Pediatric Small Organ Adult Cephalic Trans-vaginal Trans-rectal Musculo-skeletal Gynecological Cardiac Adult Trans-Esoph. (Cardiac) Peripheral Vessel	Identical
Reusable?	Yes	Yes	Identical
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Identical
Scientific Technology	Ultrasound Imaging	Ultrasound Imaging	Identical
Operating principles	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to	System console generates electrical current and sends to a connected, compatible transducer to stimulate its piezoelectric elements at the distal end. Stimulation causes the elements to	Identical

Standard Feature	Philips Sparq Diagnostic Ultrasound System K# Pending (Subject Device)	Philips Sparq Diagnostic Ultrasound System K162329 (Predicate Device)	Comparison
	expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	expand and contract which creates a high-pressured wave (i.e., soundwave). A series of soundwaves then propagate toward tissue medium (e.g., mucus membrane, bone). The transducer then receives echoed soundwaves that are reflected from the tissue medium and transmits it to the system. The system processes the echoed soundwaves into an image which is displayed on the display monitor screen of the system for user interpretation.	
Type of Previously-cleared Transducers	Curved Array Linear Array Sector Array	Curved Array Linear Array Sector Array	Identical
Acoustic Outputs Within Range?	Yes	Yes	Identical
Previously cleared Imaging Modes?	Yes	Yes	Identical
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical

Table 6: Technological Comparison of Subject Device (i.e., QLAB Advanced Quantification Software) & Predicate Device

Standard Feature	QLAB Advanced Quantification Software K# Pending (Subject Device)	QLAB Advanced Quantification Software K191647 (Predicate Device)	Comparison
Indications for Use	QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	QLAB Advanced Quantification Software is a software application package. It is designed to view and quantify image data acquired on Philips ultrasound systems.	Identical
Application Descriptions	Semiautomatic border detection, chamber identification, contour generation, measurement parameters	Semiautomatic border detection, chamber identification, contour generation, measurement parameters	Identical

VII. Performance Data

Relevant performance data does not apply to this submission. Design control measures are described within submission support a decision of substantial equivalence.

VIII. Conclusion

There are no changes in software, hardware, and intended uses of the subject devices comparing to the predicates. User labeling for the subject devices has been expanded to include information about lung and cardiac ultrasound imaging, based on established methods or the latest society guidelines, for patients with coronavirus disease 2019 (COVID-19). The results of the design controls activity support a determination that the subject devices do not raise new questions of safety or effectiveness and are substantially equivalent to the predicate devices.