Philips Ultrasound, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

September 24, 2021

Re: K212704
Trade/Device Name: Philips EPIQ Diagnostic Ultrasound System, Philips Affiniti 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, OBJ, QIH
Dated: August 25, 2021
Received: August 26, 2021

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212704

Device Name
Philips EPIQ Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of Philips EPIQ series 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, Intra-cardiac Echo, Intra-luminal, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung.

The clinical environments where Philips 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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed.

However, nothing stated in the user information reduces your responsibility for sound clinical judgement 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.

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.

510(k) Number *(if known)*

K212704

Device Name
Philips Affiniti Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of the Affiniti Series 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, Lung.

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

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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were 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.

TRADITIONAL 510(K)
Philips Ultrasound
Liver Fat Quantification Module

510(k) # K212704

510(k) Summary

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

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Tamara Daniels Senior Manager, Regulatory Affairs 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Phone: 203.213.6862
Secondary Contact Information	Anne Rossi Director, Regulatory Affairs 22100 Bothell Everett Hwy Bothell, WA 98021-8431 Phone: 425.256.0664
Date Prepared	September 21, 2021

II. Device Proprietary Name — Philips EPIQ Diagnostic Ultrasound System
Philips Affiniti Diagnostic Ultrasound System

Common Name — Diagnostic Ultrasound System and Transducers

Regulation Description: — Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system Diagnostic ultrasound transducer
Diagnostic intravascular catheter
Medical image management and processing

Product Code; **Regulation Description;** **Regulation Number**	IYN; Ultrasonic Pulsed Doppler Imaging System; 21 CFR 892.1550 IYO; Ultrasonic Pulsed Echo Imaging System; 21 CFR 892.1560 ITX; Diagnostic Ultrasonic Transducer; 21 CFR 892.1570 OBJ; Diagnostic Intravascular Catheter; 21 CFR 870.1200 QIH; Picture archiving and communications system; 21 CFR 892.2050

Device Class	Class II
Classification Panel	Radiology

III. Predicate & Reference Devices

Primary Predicate Devices:

- K202216 EPIQ Diagnostic Ultrasound System

Reference Predicate Device:

- K201012 Affiniti Diagnostic Ultrasound System
- K161843 Aplio I900/I800/I700 Diagnostic Ultrasound System, V2.0 Toshiba Medical Systems Corporation (also marketed under Canon)

IV. Device Description

The purpose of this Traditional 510(k) Pre-Market Notification is to introduce the following two new Liver Fat Quantification software features:

(1) Attenuation Quantification: *a measure of the attenuation coefficient in dB/cm-MHz of a region of interest in the liver*
(2) Hepato-Renal Index Quantification: *a ratio measure of the echogenicity ('brightness') of the liver parenchyma relative to that of the adjacent renal cortex*

The features provide the end user with the capability to calculate attenuation of the liver and an hepato-renal index ratio during an ultrasound exam using Philips EPIQ or Affiniti Ultrasound System. Previously cleared liver quantification tools available to the end user include Shear Wave Point Quantification (ElastPQ, cleared via K17207 on 04 Oct 2017) and Shear Wave Imaging (ElastQ, cleared via K181485 on 27 Jul 2018). These existing quantification features measure liver stiffness on real-time and retrospective images.

The Philips EPIQ and Affiniti Series Diagnostic Ultrasound Systems were selected as the primary predicate for the subject device. The technology is similar to the cleared Aplio I900/I800/I700 Diagnostic Ultrasound System, V2.0. This product contains attenuation and hepato-renal index quantification features.

V. Indications for Use

Device	Indications for Use

Philips EPIQ Diagnostic Ultrasound System	The intended use of Philips EPIQ series 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, Intra-cardiac Echo, Intra-luminal, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal, Lung. The clinical environments where Philips 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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were 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 Series 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, Lung. The clinical environments where the Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients. 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. Systems are to be operated only by appropriately trained healthcare professionals for the purposes for which they were designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

VI. Comparison of Technological Characteristics with the Predicate Device

The selection of the predicate device (K202216, K201012) is based on the similarity in indications for use, clinical use scenarios, and principles of operation among devices. The introduction of the Liver Fat Quantification software features does not modify the Philips EPIQ and Affiniti Ultrasound System indications. The current Liver Quantification tools available to the end user include Shear Wave Point Quantification (ElastPQ) and Shear Wave Imaging (ElastQ).

The Liver Fat Quantification software feature functionalities allow the end user to perform the following measurements during an ultrasound exam:

(1) Attenuation Quantification: *a measure of the attenuation coefficient in dB/cm-MHz of a region of interest in the liver*
(2) Hepato-Renal Index (HRI) Quantification: *a ratio measure of the echogenicity ('brightness') of the liver parenchyma relative to that of the adjacent renal cortex*

The selection of the reference device (K161843) is based on the similar of software feature functionality. This reference device contains the software features (attenuation and hepato-renal index ratio quantifications) included in this submission.

VII. Performance Data

The proposed Philips Liver Fat Quantification software features were tested in accordance with Philips internal processes. Design Control activities to assure the safe and effective performance of the Liver Fat Quantification software features include but are not limited to the following:

- Requirements Review
- Risk Analysis and Management
- Product Specifications
- Design Reviews
- Software Verification and Validation

Non-clinical bench performance testing was also conducted for attenuation imaging on the Canon device to the proposed Liver Fat Quantification software features.

Software Verification and Validation testing were used to support evidence for the new Liver Fat Quantification software features. The software documentation is presented in accordance with the FDA's *Guidance for Content of Premarket Submissions for Software Contained in Medical Devices* issued May 11, 2005.

VIII. Conclusion

Based on adherence to the aforementioned Philips internal processes and the successful verification and validation testing, the proposed Liver Fat Quantification software features are similar to the software feature in the reference device K161843. The proposed devices meet the defined requirements and performance claims and are substantially equivalent to the proposed primary predicate device (K202216).