March 6, 2020

Philips Ultrasound, Inc.
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K200304
Trade/Device Name: EPIQ 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: February 5, 2020
Received: February 6, 2020

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); 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,

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)*

K200304

Device Name

EPIQ Diagnostic Ultrasound System

Indications for Use *(Describe)*

The intended use of the EPIQ Diagnostic Ultrasound System is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use:

Abdominal, Cardiac Adult, Cardiac other (Fetal Echo), 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 Philips EPIQ Diagnostic Ultrasound Systems and Philips 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 and used 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 user 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.

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510(k) Summary

Philips EPIQ Series Diagnostic Ultrasound Systems

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

1. **Submitter's name, address, telephone number, contact person.**

Philips Ultrasound, Inc.

22100 Bothell Everett Hwy

Bothell, WA 98021-8431

Contact person: Linda Schulz, Sr. Regulatory Affairs Specialist

Email: linda.schulz@philips.com

Tel: 425-487-7127
Fax: 425-487-8666

Secondary Contact: Hebe Sun, Regulatory Affairs Manager

Email: hebe.sun@philips.com

Date prepared: January 15, 2020

2. **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common name: Diagnostic ultrasound system and transducers

Proprietary name: EPIQ Series Diagnostic Ultrasound System

These devices are classified as follows:

Classification Description	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

As stated in 21 CFR, parts 892.1550, 892.1560, and 892.1570, each of these generic types of devices has been classified as Class II.

3. Indications for Use

The intended use of the 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 Echo), 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 Philips EPIQ Series 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 and used 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 user responsibility for sound clinical judgement and best clinical procedure.

4. Device Description

The proposed Philips EPIQ Series Diagnostic Ultrasound Systems are general purpose, software controlled, diagnostic ultrasound systems. Their function is to acquire ultrasound data and to display the data in various modes of operation. The devices consist of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics and optional peripherals (ECG, printers).

Transducers are connected to the system using a plug in electrical connection. Other than the introductions of the new mC12-3 Transducer, the device description, accessories and components are unchanged. See **Table 1** below for technical comparison of the subject device and the predicate device.

5. Substantially Equivalent Devices

Philips Ultrasound believes the proposed Philips EPIQ Series Diagnostic Ultrasound Systems with mC12-3 Transducer is substantially equivalent to the following currently marketed devices:

Primary Predicate:

K1812857
Philips EPIQ Series Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System

A comparison of the subject device Philips EPIQ Series Diagnostic Ultrasound System with mC12-3 Transducer to the currently marketed and predicate device, Philips EPIQ Series Diagnostic Ultrasound Systems is provided in **Table 1** below:

TABLE 1

Comparison of the proposed Philips EPIQ Series Diagnostic Ultrasound System to the currently marketed and predicate device, Philips EPIQ Series Diagnostic Ultrasound System

Feature		Subject Device mC12-3 Transducer	Primary Predicate C8-5 Transducer (K182857)	Reference Device C9-2 Transducer (K182857)	Comparison
Indications for Use		Same as EPIQ K182857	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal), Peripheral Vessel, Cerebral Vascular,		Same
Clinical application		Abdominal, Pediatric, Neonatal Cephalic, Peripheral Vessel	Abdominal, Pediatric, Neonatal Cephalic, Peripheral Vessel	Fetal / OB, abdominal, pediatric, musculo-skeletal, GYN, Urology, peripheral vessel, and Fetal Echo	Indications identical to C8-5
Acoustic Output		ISPTA.3 ≤ 720 (mW/cm2) TI ≤ 6.0 MI ≤ 1.9	Same	Same	Same
Physical Characteristics	**Broadband Frequency Range**	12-3 MHz	8-5 MHz	9-2 MHz	Within range of all EPIQ Transducers (18-2 MHz)
	Geometrical Configuration	Curved Array	Curved Array	Curved Linear	Same as C8-5
	Total number of elements	160	128	192	Within the same range
	Field of View	94.9°	122°	102°	Narrower field of view

6. Safety Considerations

The subject Philips EPIQ Series Diagnostic Ultrasound System with mC1203 Transducer is a Track 3 Device and complies with the referenced standard as well as the FDA ultrasound guidance document, Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued on June 27, 2019.

7. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed mC12-3 Transducer with the Philips EPIQ Series Diagnostic Ultrasound System:

- ANSI/AAMI 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO 10993-1: Biological evaluation of medical devices – Part 1:Evaluation and testing within a risk management process; 2018
- 10993-5 Biological evaluation of medical devices – Part 5:Tests for in vitro cytotoxicity, 2009
- ISO 10993-10: Biological evaluation of medical devices – Part 10:Tests for irritation and skin sensitization, 2010
- ISO 10993-12: Biological evaluation of medical devices – part 12: sample preparation and reference materials, 2012

There are no device specific performance standards the proposed Philips EPIQ Series Diagnostic Ultrasound System with mC12-3 Transducer.

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures.

8. Clinical Data

The proposed Philips EPIQ Series Diagnostic Ultrasound System did not require clinical data for determination of substantial equivalence.

9. Sterilization

No components are supplied sterile.

10. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed Philips EPIQ Series Diagnostic Ultrasound Systems with the new mC12-3 transducer meet their intended use. The subject device and predicate device:

- indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- have the same gray-scale and Doppler capabilities.
- use essentially the same technologies for imaging, Doppler functions and signal processing.
- have acoustic output levels within the Track 3 FDA limits.
- manufactured under equivalent quality systems.
- manufactured of materials with equivalent bio safety.
- designed and manufactured to the same electrical and physical safety standards.

The differences between the subject device and predicate device do not raise new questions of safety and/or effectiveness. Therefore, the proposed Philips EPIQ Series Diagnostic Ultrasound System with mC12-3 Transducer is substantially equivalent to the predicate Philips EPIQ Series Diagnostic Ultrasound Systems in terms of safety and effectiveness.