April 28, 2025

Philips Ultrasound LLC
Irma Sandoval-Watt
Principal Regulatory Affairs Specialist
22100 Bothell Everett Highway
Bothell, Washington 98021

Re: K250030
Trade/Device Name: Flash Ultrasound System 5100 Point of Care
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 6, 2025
Received: January 6, 2025

Dear Irma Sandoval-Watt:

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250030

Device Name

Flash Ultrasound System 5100 Point of Care (5100 POC, 5100 POC Pro)

Indications for Use *(Describe)*

The Flash Ultrasound System 5100 Point of Care (5100 POC and 5100 POC Pro) is indicated for diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal
Adult Cephalic
Cardiac Adult
Cardiac Pediatric
Cerebral Vascular
Fetal/OB
Lung
Musculoskeletal (Conventional)
Musculoskeletal (Superficial)
Neonatal Cephalic
Ophthalmic
Other: Carotid
Other: GYN
Pediatric
Peripheral Vessel
Small Organ (Breast, Thyroid, Testicle)
Trans-Esophageal (Cardiac)
Trans-Vaginal

Modes of operation include: B Mode (or 2D), Color Doppler, Color Power Angio Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-Mode (including anatomical M-Mode), Harmonics (Tissue), and Combined modes.

The clinical environments where the Flash Ultrasound System 5100 POC may be used are: hospitals, surgery centers, clinics, physicians' offices, diagnostic centers, critical care and emergency room environments, and point-of-care clinical settings 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 the user's 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.

PHILIPS

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

510(k) Number: K250030

1. Submitter's name, address, telephone number, contact information

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Date Prepared: 17 April 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: Flash Ultrasound System 5100 Point of Care

Common Name: Diagnostic Ultrasound System and Transducers

Regulatory Description:

Classification Description	21 CFR §	Product Code
Primary		
System, imaging, pulsed doppler, ultrasonic	892.1550	IYN
Secondary		
System, imaging, pulsed echo, ultrasonic	892.1560	IYO
Transducer, ultrasonic, diagnostic	892.1570	ITX

Device Class: Class II

Review Panel: Radiology

Predicate Device: K162329, CX50 and Sparq Ultrasound Diagnostic Systems

Reference Device: K222648, 5000 Compact Series Ultrasound Systems
K231190, EPIQ Series Diagnostic Ultrasound System

3. Device Description

The purpose of this Traditional 510(k) Pre-*Market Notification is to introduce the Flash Ultrasound System 5100 Point of Care (POC)* device into the point-of-care environment. The *Flash Ultrasound System 5100 POC* is constructed with assets from the previously cleared 5000 Compact Series hardware platform (K222648) and a new Rhythm software platform that is new to the POC environment.

The *Flash Ultrasound System 5100 POC* supports a full touch screen interface on the main display as the primary means of directing the system, leveraging customer familiarity with smart devices and the ease of cleaning and maintenance of a pure glass surface.

Additionally, *Flash Ultrasound System 5100 POC* is designed to fit into tight spaces in a crowded Emergency Room (ER) with its small footprint, sleek design, and a large vertical tablet with ergonomic controls. The new Rhythm software offers point-of-contact workflow enhanced with assisted needle visualization, streamline point-of-care workflows such as flexible patient data management and AutoStrain EF. In addition to these POC workflows, the Rhythm software provides enhanced responsiveness with an easy-to-learn user interface as all controls are located in the same plane as the user's eye and hand for working more efficiently with the patient. The *Flash Ultrasound System 5100 POC* has two models, the 5100 POC and the 5100 POC Pro. The 5100 POC version does not support two transducers, C5-1 and X8-2t; however, the 5100 POC Pro supports all the transducers listed for the system.

4. Indications For Use

The *Flash Ultrasound System 5100 Point of Care* (5100 POC and 5100 POC Pro) is indicated for diagnostic ultrasound imaging and fluid flow analysis of the human body, with the following indications for use:

Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Cerebral Vascular, Fetal/OB, Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Neonatal Cephalic, Ophthalmic, Other: Carotid, Other: GYN, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Trans-Esophageal (Cardiac), Trans-Vaginal.

Modes of operation include B Mode (or 2D), Color Doppler, Color Power Angio Doppler, Continuous Wave Doppler, Pulse Wave Doppler, Tissue Doppler, M-Mode (including anatomical M-Mode), Harmonics (Tissue), and Combined modes.

The clinical environments where the *Flash Ultrasound System 5100 POC* may be used are: hospitals, surgery centers, clinics, physicians' offices, diagnostic centers, critical care and emergency room environments, and point-of-care clinical settings 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 the user's responsibility for sound clinical judgment and best clinical procedure.

5. Technological Comparison to Predicate Devices

The *Flash Ultrasound System 5100 POC* has the same intended use as the predicate device and the reference devices of diagnostic ultrasound imaging and fluid flow analysis. The *Flash Ultrasound System 5100 POC* has identical intended users and use environments as the predicate device, and it does not introduce any new transducers, nor does it change indications for any existing transducers. All transducers' indications for use are already present on other cleared Philips Ultrasound Systems. The *Flash Ultrasound System 5100 POC* does have a new software platform, Rhythm; however, this platform is equivalent to the predicate's software platform.

6. Safety Considerations

The proposed *Flash Ultrasound System 5100 POC* with all C5-1, C6-2, C8-5, C9-4V, L12-3ERGO, eL18-4, mL26-8, S5-1, S8-3, X7-2t, and X8-2t transducers, are all Track 3 devices and comply with the reference standards and with the FDA ultrasound guidance document, *Guidance for Industry and FDA Staff – Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*, February 21, 2023.

7. Non-Clinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed *Flash Ultrasound System 5100 POC*:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic and essential performance
- IEC 60601-1-2: 2014+AMD1:2020 Medical Electrical Equipment – Part 1-2: General requirements for safety; electromagnetic compatibility – requirements and tests
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral standard: usability
- IEC 60601-2-37:2024 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 60601-2-18:2009 Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 62304:2006+AMD1:2015 Medical Device Software – Software life cycle process
- IEC 62359:2010+AMD1:2017 CSV Ultrasonics – Field Characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field
- IEC 62366-1:2015+AMD1:2020 Medical devices – Application of usability engineering to medical devices
- ISO 14971:2019 Medical devices – Application of risk management to medical devices

Non-Clinical verification testing has been performed addressing system level requirements according to system and design specifications, and risk control measures. Design Control activities to assure the safety and effectiveness of the *Flash Ultrasound System 5100 POC* include but are not limited to the following:

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

The *Flash Ultrasound System 5100 POC* user interface has been found to be safe and effective for the intended uses and use environments. Biocompatibility testing is not needed for the proposed *Flash Ultrasound System 5100 POC* device as the transducers patient contacting materials and manufacturing processes are not impacted by the introduction of the proposed *Flash Ultrasound System 5100 POC*. Furthermore, the common plastic/metal parts used in the external customer facing equipment are also used in other Philips Ultrasound systems.

8. Clinical Data

The proposed *Flash Ultrasound System 5100 POC* did not require clinical data for determination of substantial equivalence, with substantial equivalence being demonstrated based on the following attributes:

- Design features
- Indications for use
- Fundamental scientific technology
- Non-clinical performance testing
- Safety and effectiveness

9. Sterilization

The proposed *Flash Ultrasound System 5100 POC* is not provided sterile; therefore, this is not applicable.

10. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed *Flash Ultrasound System 5100 POC* met the intended use.

The proposed *Flash Ultrasound System 5100 POC* has identical indications compared to the predicate, Sparq (K162329), and previously cleared reference devices, 5000 Compact Series (K222648) and EPIQ Series (K231190). The design changes do not significantly affect the use of the device, nor do they introduce any new or significantly modified risks. The differences between the proposed *Flash Ultrasound System 5100 POC* and the predicate do not raise new questions of safety and effectiveness. Therefore, the proposed *Flash Ultrasound System 5100 POC* is substantially equivalent to the predicate and reference devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.