Philips Ultrasound, Inc.
% Tamara Daniels
Sr. Regulatory Affairs Manager
22100 Bothell Everett Highway
BOTHELL WA 98201

September 24, 2021

Re: K212777
Trade/Device Name: Collaboration Live
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, IYN, IYO
Dated: August 27, 2021
Received: September 1, 2021

Dear Tamara Daniels:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212777

Device Name
Collaboration Live

Indications for Use *(Describe)*
Collaboration Live is indicated for remote console access of the Philips ultrasound system for diagnostic image viewing and review, consultation, guidance, support, and education in real time. Access must be granted by the healthcare professionals operating the ultrasound system. Compliance with the technical and operator requirements specified in the User Manual is required.

It is the responsibility of the healthcare professionals at the remote client to ensure image quality, display contrast, and ambient light conditions are consistent with the generally accepted standards of the clinical application.

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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510(k) Summary

510(K) #: K212777

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

Date Prepared: September 21, 2021

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Courtney Nix Senior Regulatory Affairs Specialist
Secondary Contact	Tamara Daniels Senior Regulatory Affairs Manager

II. Device

Trade Name	Collaboration Live
Common Name	System, Image Processing, Radiological
Product Code; Regulation Description; Regulation Number	LLZ; System, Image Processing, Radiological; 21 CFR 892.2050 IYN; System, Imaging, Pulsed Doppler, Ultrasonic; 21 CFR 892.1550 IYO; System, Imaging, Pulsed Echo, Ultrasonic; 21 CFR 892.1560
Device Class	Class II
Review Panel	Radiology
Predicate Device	Collaboration Live – Philips Ultrasound (K201665, cleared September 15, 2020)

III. Device Description

Collaboration Live is software-based communication feature integrated with Philips Diagnostic Ultrasound Systems. Collaboration Live, together with remote-client Reacts software, enables two-way communication of text, voice, image, and video information between an ultrasound local system operator and a remote healthcare professional on a Windows, iOS, Android, or Chrome platform. Collaboration Live-Reacts facilitates: 1) remote diagnostic viewing and review, 2) remote clinical training and education, 3) remote peer-to-peer collaboration, and 4) remote service support. Collaboration Live functionality includes a remote-control feature in which the ultrasound local system operator may grant a qualified remote user control of the ultrasound system parameters via a virtual control panel and virtual touch screen. By meeting the technical, operator, and environment requirements specified in the User Manual, healthcare professionals, using Reacts, may provide clinical diagnoses from a remote location as they would directly on the ultrasound system.

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IV. Indications for Use

Collaboration Live is indicated for remote console access of the Philips ultrasound system for diagnostic image viewing and review, consultation, guidance, support, and education in real time. Access must be granted by the healthcare professionals operating the ultrasound system. Compliance with the technical and operator requirements specified in the User Manual is required.

It is the responsibility of the healthcare professionals at the remote client to ensure image quality, display contrast, and ambient light conditions are consistent with the generally accepted standards of the clinical application.

V. Comparison of Technological Characteristics with the Predicate Device

The primary purpose of the submission is to expand the compatible platforms for Collaboration Live:

- Predicate (K201665): Windows
- This submission: Windows, iOS, Android, and Chrome

Additional features have been introduced into the proposed software:

- Network Indicator
- Remote Image Quality
- Remote User Measurement

The intended users, use environment, indications for use, and intended use are unchanged as compared to the predicate.

VI. Validation Testing Summary

Validation testing was completed and produced under Philips's design controls procedures that that comply with 21 CFR 820.30. Validation Testing, with pre-determined criteria, was conducted to evaluate and demonstrate the equivalency of Collaboration Live used on Windows, iOS, Android, and Chrome platforms.

VII. Conclusion

The results of the design control activities support that the software, which expands the compatible platforms and adds three features, does not raise new questions of safety or effectiveness. In addition to labeling, testing performed demonstrates that the Collaboration Live software meets the defined requirements and performance claims and are substantially equivalent to the predicate software (K201665).