Philips Ultrasound, Inc.
% Mr. Colin S. Jacob
Senior Regulatory Affairs Specialist
22100 Bothell Everett Highway
BOTHELL WA 98021

September 15, 2020

Re: K201665
Trade/Device Name: Collaboration Live
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, IYN, IYO
Dated: August 10, 2020
Received: August 11, 2020

Dear Mr. Jacob:

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)*
K201665

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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K201665

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.
Date Prepared: September 14, 2020

I. Submitter

Manufacturer Name and Address	Philips Ultrasound, Inc. 22100 Bothell Everett Hwy Bothell, WA 98021-8431
Contact Information	Colin S. Jacob Senior Regulatory Affairs Specialist TEL: +1 (425)-908-1209 EMAIL: colin.jacob@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	Collaboration Live
Common Name	System, Image Processing, Radiological
Regulation Description	Picture archiving and communications system (Primary) Ultrasonic pulsed doppler imaging system Ultrasonic pulsed echo imaging system
Regulation Number	892.2050 (Primary) 892.1550 892.1560
Product Code	LLZ (Primary) IYN IYO
Device Class	Class II
Review Panel	Radiology

I. Predicate Device

Collaboration Live – Philips Ultrasound (K200179)

II. Device Description

Collaboration Live is software-based communication feature integrated in Philips Diagnostic Ultrasound Systems. Collaboration Live together with remote-client Reacts 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 device. 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.

III. 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.

IV. Comparison of Technological Characteristics with the Predicate Device

Attribute	Collaboration Live K201665 (Subject Device)	Collaboration Live K200179 (Predicate)	Comparison
Manufacturer	Philips Ultrasound, Inc.	Philips Ultrasound, Inc.	**Same**
Regulation Name	Picture Archiving and Communications System (PACS)	Picture Archiving and Communications System (PACS)	**Same**
Product Code(s)	Primary: LLZ Secondary: IYN, IYO	Primary: LLZ Secondary: IYN, IYO	**Same**
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.	Collaboration Live is indicated for remote console access of the Philips ultrasound system for image viewing, image review, consultation, guidance, support, and education in real time. Access must be granted by the technologist operating the system. Images reviewed remotely are not for diagnostic use.	Both device are indicated for image review and viewing at remote location over the Internet. They are intended for ultrasound image review and viewing, remote control, and communication in real time. The predicate is not indicated for diagnostic use.
Features	Image viewing and review Text Chat Voice Calling Video Calling Remote Asset Sharing Remote Control	Image viewing and review Text Chat Voice Calling Video Calling Remote Asset Sharing Remote Control	**Same**
Local System Hardware	Philips EPIQ or Affiniti ultrasound system	Philips EPIQ or Affiniti ultrasound system	**Same**
Remote System Hardware	Commercially available off-the-shelf computer hardware	Commercially available off-the-shelf computer hardware	**Same**

Attribute	Collaboration Live K201665 (Subject Device)	Collaboration Live K200179 (Predicate)	Comparison
Supported Imaging Modalities	Ultrasound	Ultrasound	**Same**
Intended Users	Qualified healthcare professionals	Qualified healthcare professionals	**Same**
Remote-client Use Environment	Clinical environment with ambient light condition consistent with the generally accepted standards of the clinical application.	Clinical environment	Subject device has an additional requirement for ambient light condition.
Remote Diagnostic Use	Image visualized for diagnostic review and viewing on remote-client Reacts	No	The predicate is not indicated for diagnostic use.

V. Validation Testing Summary

Validation testing with pre-determined criteria was conducted to evaluate the equivalency of remote viewing and review comparing to local ultrasound systems using Collaboration Live and remote-client Reacts. Remote display specifications and network bandwidth requirements for equivalent image quality for diagnostic viewing were determined. Labeling materials have been updated to inform the users regarding the requirements for safe and effective remote diagnostic review and viewing.

VI. Conclusion

The device functionalities, intended users, and performance of the subject Collaboration Live software, remote-client Reacts, and Philips diagnostic ultrasound systems, which Collaboration Live runs on, remain unchanged comparing to the predicate.

The change in indications for use of ultrasound images to be viewed and reviewed remotely for diagnostic purpose on remote-client Reacts, increases options to image patients inside and outside of healthcare facilities, expands the number of healthcare professionals capable of performing ultrasound imaging technique, which could help limit the risk of exposure for healthcare workers and patients to the infectious diseases such as COVID-19.

The results of the design control activity suggest that the subject device does not raise new questions of safety or effectiveness. The validation testing and labeling are adequate to support the substantial equivalent determination to the predicate device.