Philips Healthcare
℅ Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

February 18, 2020

Re: K200179
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: November 25, 2019
Received: January 24, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200179

Device Name
Collaboration Live

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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(5) 510(k) Summary of Safety and Effectiveness

Collaboration Live

The 510(k) summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92**.** See Appendix D1.

1. **Submitter's name, address, telephone number, contact person.**
   Philips Ultrasound, Inc.
   22100 Bothell Everett Hwy
   Bothell, WA 98021-8431

   Contact person: Paul Elias, Regulatory Affairs Specialist
   Email: Paul.Elias@philips.com
   Tel: 425-482-8396
   Fax: 425-487-8666
   Secondary Contact: Hebe Sun, Senior Regulatory Affairs Manager
   Email: Hebe.Sun@philips.com

   Date prepared: November 20, 2019

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: Picture archiving and communications system
   Proprietary name: Collaboration Live

Classification Name	21 CFR Section	Product Code
System, Image Processing, Radiological Picture archiving and communications system (PACS)	892.2050	LLZ
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO

   As stated in 21 CFR parts 892.2050, 892.1550, and 892.1560, each of these types of devices has been classified as Class II.

3. **Substantially Equivalent Devices**

   Philips Ultrasound believes that Collaboration Live is substantially equivalent to the following predicate device:

Philips Ultrasound, Inc.	Traditional 510(k) **Collaboration Live**

Predicate Device	510(k)
GE Customer Remote Console	K150193

4. Device Description

Collaboration Live is a new software feature integrated in Philips Epiq and Affiniti Diagnostic Ultrasound Systems (K182857). Collaboration Live enables two-way communication of text, voice, image, and video information between an ultrasound system operator and a remote user on a Windows desktop or laptop computer. Collaboration Live facilitates: 1) remote service support, 2) remote clinical training and education, and 3) remote peer-to-peer collaboration (non-diagnostic). Collaboration Live functionality includes a remote control feature in which the ultrasound system operator may grant a qualified remote user control of all ultrasound system parameters via a virtual control panel and virtual touch screen. The ultrasound system operator maintains the ability to take back system control at any time. The remote user interacts with the ultrasound system using the Collaboration Live remote application, which is called Reacts.

5. Indications for Use

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.

6. Technological Comparison to Predicate Device

Collaboration Live employs the same fundamental scientific technology as the predicate GE Customer Remote Console (CRC). Like CRC, Collaboration Live is a software feature that enables remote image viewing and real-time communication between the system operator and a remote user (on a laptop or desktop computer) for the purposes of service, training/education, and peer-to-peer collaboration. Collaboration Live also contains a remote control feature similar to CRC, in which a qualified remote user can control the system parameters when granted access by the system operator. Like CRC, remote control in Collaboration Live can be granted to only one remote user at a time and may be revoked at any time by the system operator.

7. Safety Considerations and Nonclinical Performance Testing

No performance standards for PACS systems or components have been issued under the authority of Section 514.

Quality assurance measures applied to the product design and development included risk analysis, product specifications, design reviews, and verification testing.

Software verification supported a determination of substantial equivalence with the predicate GE Customer Remote Console (K150193), and demonstrated that Collaboration Live meets the acceptance criteria and is adequate for its intended use.

8. Clinical Data

Collaboration Live did not require clinical testing to support a determination of substantial equivalence.

9. Conclusion

The Collaboration Live software requirements have been successfully verified and cybersecurity vulnerability testing has been conducted to ensure product security. The differences between Collaboration Live and the predicate GE Customer Remote Console do not raise new questions of safety or effectiveness. With similar technology, features, and indications for use, Collaboration Live is substantially equivalent to the predicate GE Customer Remote Console (K150193).

514 Performance Standards

There are no Sec. 514 performance standards for Collaboration Live.

Prescription Status

Collaboration Live and the associated Epiq and Affiniti Diagnostic Ultrasound Systems are prescription devices. The prescription device statement appears in the labeling for the Collaboration Live feature and in the labeling for the Epiq and Affiniti Diagnostic Ultrasound Systems.

Sterilization Sites

Not applicable. Collaboration Live is a software feature.