November 18, 2024

Philips Healthcare (Suzhou) Co., Ltd
℅ Yael Curtz
Regulatory Affairs Team Lead
No. 258, Zhongyuan Road, Suzhou Industrial Park
Suzhou Jiangsu, 215024
CHINA

Re: K242329
Trade/Device Name: CT Collaboration Live
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, JAK
Dated: October 30, 2024
Received: October 30, 2024

Dear Yael Curtz:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiologic Imaging
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Office of Product Evaluation and Quality
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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)*

K242329

Device Name

CT Collaboration Live (728290)

Indications for Use *(Describe)*

CT Collaboration Live is indicated for remote communication with CT console (via chat, call, video call, screen sharing and remote access) by a qualified remote clinical user for consultation, guidance, support, and training in real time. Remote access must be granted by the CT technologist operating the system. Remote access is only available for Philips CT systems supporting CT Collaboration Live connectivity capabilities. 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.

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K242329

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: August 5, 2024

Manufacturer: Philips Healthcare (Suzhou) Co., Ltd.
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Establishment Registration Number: 3009529630

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Device:	Trade Name:	CT Collaboration Live
	Common name:	Picture archiving and communications system
	Classification Name:	System, Image Processing, Radiological Picture archiving and communications system (PACS)
	Classification Regulation:	21 CFR 892.2050 21 CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	LLZ
	Secondary Product Code:	JAK
Primary Predicate Device:	Trade Name:	Collaboration Live
	Manufacturer:	Philips Ultrasound, Inc.
	510(k) Clearance:	K200179 (Predicate)
	Classification Name:	System, Image Processing, Radiological Picture archiving and communications system (PACS)
	Classification Regulation:	21 CFR 892.2050 21 CFR 892.1550 21 CFR 892.1560
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ
	Secondary Product Code:	IYN, IYO

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Device Description:

The proposed CT Collaboration Live is a software application integrated in Philips Computed Tomography (CT) X-Ray CT 5300 Systems. CT Collaboration Live enables two-way communication of text, voice, image, and video information between a CT system operator and a remote user on a Windows device. CT Collaboration Live facilitates: 1) peer-to-peer consultation and training, 2) system-level remote sharing & operation, 3) access to live image feed and 4) remote expert user(s) and physician consultation. CT Collaboration Live functionality includes a remote-control feature in which the CT system operator may grant a qualified remote user control of the CT system parameters via a virtual control panel and virtual touch screen.

Intended Use:

CT Collaboration Live is a solution with on-console chat, audio and video call, screen sharing and remote access functionality to facilitate collaboration between CT users and between CT user and Philips Clinical Application Specialist.
Contraindications are not known.

Indications for Use:

CT Collaboration Live is indicated for remote communication with CT console (via chat, call, video call, screensharing and remote access) by a qualified remote clinical user for consultation, guidance, support, and training in real time. Remote access must be granted by the CT technologist operating the system. Remote access is only available for Philips CT systems supporting CT Collaboration Live connectivity capabilities. Images reviewed remotely are not for diagnostic use.

Technological Characteristics

The proposed CT Collaboration Live has the same fundamental design characteristics as the predicate Collaboration Live (K200179). CT Collaboration Live is a software application 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. CT Collaboration Live also contains a remote-control feature similar to Collaboration Live, in which a qualified remote user can control the system parameters when granted access by the system operator. Like Collaboration Live, remote control in CT Collaboration Live can be granted to only one remote user at a time and may be revoked at any time by the system operator.
Based on the information provided above, the CT Collaboration Live is considered substantially equivalent to the primary currently marketed and predicate device Collaboration Live (K200179) in terms of fundamental design technology.

The following table 1 lists the technological characteristics differences for the proposed CT Collaboration Live:

Table 1 – Technological Characteristics Comparison

Design Feature	Cleared to Market Predicate Device: Collaboration Live (K200179)	Proposed Device: CT Collaboration	Conclusion
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	**Identical,** therefore substantially equivalent.

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Regulation Name	System, Image processing, Radiological-Picture Archiving and Communications System (PACS)	System, Image processing, Radiological-Picture Archiving and Communications System (PACS)	**Identical,** therefore substantially equivalent.
Product Code	LLZ	LLZ	**Identical,** therefore substantially equivalent.
Features	Remote service support, Remote clinical training and education, Remote peer to peer collaboration (non-diagnostic)	Peer to peer consultation and training, System level remote sharing and operation, Access to live image feed, Remote expert user(s) and physician consultation	Features were elaborated for clarity. **Equivalent,** no impact to safety and effectiveness, therefore substantially equivalent.
Remote Access Control	Granted by technologist at system	Granted by technologist at system	**Identical,** therefore substantially equivalent.
Remote privileges	Secure credentials	Secure credentials	**Identical,** therefore substantially equivalent.
Number of remote users per session	1	1	**Identical,** therefore substantially equivalent.
Diagnostic use	Remote images are not for diagnostic use	Remote images are not for diagnostic use	**Identical,** therefore substantially equivalent.

Based on the above, the proposed CT Collaboration Live is considered substantially equivalent to the predicate device Collaboration Live (K200179), in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

Non-clinical performance software verification testing has been performed on the proposed CT Collaboration Live.

All tests were used to support substantial equivalence of the proposed CT Collaboration Live and to demonstrate that CT Collaboration Live:

- Complies with international and FDA-recognized consensus standards and/or FDA device Specific guidance document, and;
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, CT Collaboration Live is substantially equivalent to the predicate device Collaboration Live (K200179) in terms of safety and effectiveness.

Design Verification planning and testing against Software Requirements Specification (SRS), was conducted. Software verification activities demonstrate

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that the CT Collaboration Live software application meets the design input requirements. Software requirements may be verified by manual test, automated test, inspection/analysis, or any combination of the three. Design verification also includes risk analysis/risk mitigation testing.
The traceability between the requirements and the test protocols are described in the Traceability Matrix. The Traceability Matrix also shows the overall test results per requirement. The summary and conclusion of results are provided in the System Verification Test Report.

Summary of Clinical Performance Data:

The proposed CT Collaboration Live did not require a clinical study since substantial equivalence to the predicate device Collaboration Live (K200179) was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The proposed CT Collaboration Live is substantially equivalent to the predicate device Collaboration Live (K200179) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by verification tests provided in this 510(k) premarket notification. These tests demonstrate that CT Collaboration Live complies with the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.