March 23, 2026

Philips Healthcare (Suzhou) Co., Ltd.
℅ Tiffany Zhang
Regulatory Affairs Manager
No. 258, ZhongYuan Road, Suzhou Industrial Park,
Suzhou, Jiangsu Province, 215024
CHINA

Re: K252992
Trade/Device Name: CT Rembra RT; CT Areta RT; CT Rembra
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 17, 2026
Received: February 17, 2026

Dear Tiffany Zhang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252992

Device Name
CT Rembra RT, CT Areta RT, CT Rembra

Indications for Use *(Describe)*
The proposed CT Rembra RT, CT Areta RT, and CT Rembra are Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment support, components and accessories. The system is indicated for diagnostic imaging in radiology, head and whole-body X-ray Computed Tomography applications in oncology as part of treatment preparation and radiation therapy planning, vascular, interventional, neurology and cardiology, for patients of all ages.
These scanners are intended to be used for diagnostic imaging and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs/protocols that have been approved and published by either a governmental body or a professional medical society.
*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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.

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K252992 510(k) Summary for
CT Rembra RT, CT Areta RT, CT Rembra

This 510(k) summary is provided in accordance with 21 CFR 807.92(c) and summarizes the information supporting a determination of substantial equivalence.

Legal Manufacturer

Philips Healthcare (Suzhou) Co., Ltd.

No. 258, Zhongyuan Road, Suzhou Industrial Park, Suzhou, Jiangsu, CHINA, 215024

Establishment Registration Number: 3009529630

Location of Manufacturing Site

No. 258, Zhongyuan Road, Suzhou Industrial Park, Suzhou, Jiangsu, CHINA, 215024

Establishment Registration Number: 3009529630

Advanced Technology Center MATAM, Building 34, 3100202 Haifa, Israel

Establishment Registration Number: 9617978

Submitter Contact Person

Primary Contact	**Secondary Contact**
Tiffany Zhang Regulatory Affairs Manager Phone: +86-0-18911415886 E-mail: tiffany.zhang@philips.com	Carmit Shmuel Regulatory Affairs Manager and Site Lead Phone: (972) 54-2109054 E-mail: Carmit.shmuel@philips.com

Device Name and Classification

Commerical/Trade name:	CT Rembra RT	CT Areta RT	CT Rembra
Product Name	CT 5400 RT	CT 5200 RT	CT 5400
Legal Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.		
Classification Name:	Computed tomography x-ray system		
Classification Regulation:	21 CFR 892.1750		
Classification Panel:	Radiology		
Device Class:	II		
Primary Product code:	JAK		

Predicate Device

Primary Predicate Device:

Trade Name:	CT 5300
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
510(k) Clearance:	K232491
Classification Regulation:	21 CFR 892.1750

Classification Name:	Computed tomography x-ray system
Classification Panel:	Radiology
Device Class:	II
Product Code:	JAK

Secondary Predicate Devices:

Trade Name:	Philips CT Big Bore
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K171850
Classification Regulation:	21 CFR 892.1750
Classification Name:	Computed tomography x-ray system
Classification Panel:	Radiology
Device Class:	II
Product Code:	JAK

Trade Name:	Spectral CT 7500 RT
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K240844
Classification Regulation:	21 CFR 892.1750
Classification Name:	Computed tomography x-ray system
Classification Panel:	Radiology
Device Class:	II
Product Code:	JAK

Reference device:

Trade Name:	CT Collaboration Live
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
510(k) Clearance:	K242329
Classification Regulation:	21 CFR 892.2050 21 CFR 892.1750
Classification Name:	Medical image management and processing system Computed tomography x-ray system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ, JAK

Device Description

The CT Rembra RT, CT Areta RT, and CT Rembra proposed devices have similar technological characteristics, software operating platform, and supported software characteristics as the predicate devices.

The proposed devices expand the CT product family with improved performance, workflow and functionality for oncology applications. They also provide a large-bore radiology solution on the Incisive Host software platform.

The design of the proposed CT Rembra RT, CT Areta RT, CT Rembra is based on the currently marketed CT 5300 (K232491), with hardware and software modifications. These include the

addition of new oncology software features and workflow enhancements for radiotherapy planning support.

The proposed system is a whole-body computed tomography (CT) x-ray system featuring a continuously rotating x-ray tube, detectors, and gantry with multi-slice capability. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body taken at different angles and planes. It produces CT images in DICOM format, which can be used by trained staff for post-processing applications commercially distributed by Philips. The CT images can be used by trained staff as an aid in diagnosis, treatment and radiation therapy planning as well as for diagnostic and therapeutic interventions. Only trained and qualified users, certified in accordance with country-specific regulations, are authorized to operate the system.

The proposed device has an 85 cm bore and includes a detector array that provides 60 cm scan field of view (SFOV) and 85cm extended field of view (EFOV).

The key system modules and functionalities of proposed device are: Gantry [X-ray tube assembly, HV generator, Collimator, DMS (Data Measurement System), Touch Panels], Patient Table (Couch), Console and optional components as well as accessories. This system also includes hardware and software for data acquisition, display, manipulation, storage and filming as well as post-processing into views other than the original axial images.

Upgrade Kits are available to upgrade CT Rembra RT, CT Areta RT, CT Rembra installations to the latest version in forward production.

Indications for Use
The proposed CT Rembra RT, CT Areta RT, and CT Rembra are Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of X-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment support, components and accessories. The system is indicated for diagnostic imaging in radiology, head and whole-body X-ray Computed Tomography applications in oncology as part of treatment preparation and radiation therapy planning, vascular, interventional, neurology and cardiology, for patients of all ages.

These scanners are intended to be used for diagnostic imaging and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs/protocols that have been approved and published by either a governmental body or a professional medical society.

**Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.*

Indications for Use Comparison
The indications for use of the proposed CT Rembra RT, CT Areta RT, and CT Rembra are similar to those of the predicate devices CT 5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844).

All devices are computed tomography (CT) x-ray systems intended to produce cross-sectional images of the head and body by computer reconstruction of x-ray transmission data. The devices are indicated for diagnostic imaging applications, including head and whole-body imaging, and

may be used in oncology, vascular, cardiology, and other clinical applications for patients of all ages.

The proposed devices additionally include use in oncology applications for treatment preparation and radiation therapy planning, which is consistent with the intended use of the predicate devices.

All devices are also intended for low-dose CT lung cancer screening in accordance with established screening protocols.
Therefore, the indications for use of the proposed devices are the same as those of the predicate devices, do not raise new questions of safety and effectiveness, and support a determination of substantial equivalence.

Comparison of Technological Characteristics with Predicate Devices
The proposed CT Rembra RT, CT Areta RT, and CT Rembra are computed tomography x-ray systems designed to generate cross-sectional images of the human body through a computer's reconstruction of x-ray transmission data acquired from different angles and planes. The system also includes signal analysis and display equipment, patient and equipment support, components, and accessories. The proposed device is a continuous rotation computed tomography system suitable for a range of CT applications and is used clinically as a diagnostic imaging device that produces images corresponding to tissue density. The quality of the images depends on the level and amount of X-ray energy delivered to the tissue. CT imaging displays both high-density tissue, such as bone, and soft tissue.

The technological characteristics of the proposed CT Rembra RT, CT Areta RT, CT Rembra, were compared with those of the predicate devices CT5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844). The comparison includes the following categories:

- Scanner
- Technical basis (Single/Dual layer, etc.)
- Environment of Use
- Patient Population
- Application body sites
- Kind of users
- Hardware property
  - Gantry
  - Patient table (Couch)
  - Generator and Tube
  - DMS
  - Console
- Software property
  - Software release version
  - Software features

The proposed devices have the same fundamental technological characteristics as the predicate devices. Software features of CT Rembra RT, CT Areta RT, and CT rembra have been modified compared to the predicate devices to support additional device functionality. The updated software reuses previously cleared unmodified software features from the legacy software cleared under K232491, K171850, K240844 and K242329.

Based on the comparison of technological characteristics, the proposed CT Rembra RT, CT Areta RT, and CT Rembra do not raise new questions of safety and effectiveness and support a determination that the proposed devices are substantially equivalent to the predicate devices CT5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844).

Substantial Equivalence

A summary of the technological characteristics of the proposed devices, CT Rembra RT, CT Areta RT, and CT Rembra, and their comparison to the predicate devices, CT5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844) is provided in Table 1.

Table 1. Summary of Technological Comparison and Basis for Substantial Equivalence

Category	Proposed Devices	Predicate Device(s)	Basis for Substantial Equivalence
Core technology	Whole-body CT x-ray system with continuous rotation	CT5300	Same fundamental technology
Technical basis	Single-layer detector system	CT5300	Same technological characteristics
Use environment, users, and patient population	Hospital use; trained operators; patients of all ages	CT5300	Comparable
Clinical applications	Diagnostic imaging including oncology and radiation therapy planning	CT5300, Philips CT Big Bore, Spectral CT 7500 RT	Comparable intended use
Scan operation	Continuous rotation; axial and helical scan modes	CT5300	Same fundamental operation
System architecture	Gantry, tube, detector, couch, console	CT5300	Same fundamental design
Performance characteristics	Image quality, noise, slice thickness, dose management	CT5300	Comparable performance
Dose management and standards	Complies with applicable NEMA and regulatory standards	CT5300	Comparable
Software platform	Incisive Host Platform (updated version)	CT5300 (prior version)	Modified; supported by verification and validation testing
Bore size / geometry	85 cm bore	Philips CT Big Bore	Comparable design supported by predicate
Field of view (EFOV)	Up to 85 cm EFOV	Philips CT Big Bore, Spectral CT 7500 RT	Modified; supported by predicate technology and testing
Image resolution	Improved high-resolution performance	CT5300	Modified; supported by testing
Detector	Updated detector elements	CT5300	Modified; supported

configuration			by testing
Oncology / RT workflow	OnPlan and RT workflow enhancements	CT 5300, Spectral CT 7500 RT, Philips CT Big Bore	Comparable functionality
Advanced imaging features	Pulmonary gating (4D CT) Extended field of view (EFOV), CT Collaboration Live, Precise Position, Precise Intervention	CT 5300, Spectral CT 7500 RT, Philips CT Big Bore	Comparable functionality
New software features	MM Sim auto-launch, CANOpen injection, Body perfusion	Not present in predicate devices	New features supported by verification and validation testing

The proposed CT Rembra RT, CT Areta RT, and CT Rembra have the same intended use and the same fundamental technological characteristics as the predicate devices CT5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844).

Differences in technological characteristics, including hardware modifications, software updates, and additional features, are supported by non-clinical performance testing or are comparable to features in the predicate devices. These differences do not raise new questions of safety and effectiveness and support a determination that the proposed devices are substantially equivalent to the predicate devices.

Performance Data

The non-clinical performance testing, including system and sub-system, phantom testing, cybersecurity, usability, interoperability, IEC/EMC and external IQ assessment, was conducted for the proposed CT Rembra RT, CT Areta RT, and CT Rembra during product development. These testing activities support the modifications described in this Premarket Notification and were conducted to demonstrate that the proposed devices are as safe and effective as the predicate devices.

Non-clinical performance testing demonstrates compliance with applicable international standards, FDA-recognized consensus standards, and regulatory requirements. The following standards were applied, as appropriate, to support the evaluation of device safety and performance:

Table 2. Applicable Standards

Standard	Title / Description	FDA Recognition Number
AAMI / ANSI ES60601-1:2005/(R)2012 + amendments (Incl. AMD2:2021)	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)	19-46

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IEC 60601-1-2 Ed. 4.1 (2020)	Medical Electrical Equipment – Electromagnetic disturbances (EMC) requirements and tests	19-36
IEC 60601-1-3 Ed. 2.2 (2021)	Radiation protection in diagnostic X-ray equipment	12-336
IEC 60601-1-6 Ed. 3.2 (2020)	Usability engineering for medical electrical equipment	5-132
IEC 60601-2-44 Ed. 3.2 (2016)	Particular requirements for CT equipment safety and performance	12-302
IEC 62304 Ed. 1.1 (2015)	Medical device software – Software lifecycle processes	13-79
IEC 62366-1 Ed. 1.1 (2020)	Application of usability engineering to medical devices	5-129
ISO 14971 (2019)	Application of risk management to medical devices	5-125
ISO 10993-1 (2018)	Biological evaluation of medical devices – Part 1	2-258
NEMA XR 25-2019	CT Dose Check	12-325
NEMA XR 26:2020	Access Controls for CT: Identification, Interlocks, and Logs	—
NEMA XR 28-2018 (R2023)	User information and system function related to dose in CT	12-330
NEMA XR 29-2013	Standard attributes related to dose optimization and management	—

Table 3. Applicable Guidance Documents

Guidance Document	Issue Date
Guidance for the Content of Premarket Submissions for Device Software Functions	June 14, 2023
Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices	Sep 6, 2017
Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	June 27, 2025
Pediatric Information for X-ray Imaging Device Premarket Notifications	Nov 28, 2017
Applying Human Factors and Usability Engineering to Medical Devices	Feb 3, 2016
Medical X-Ray Imaging Devices Conformance with IEC Standards	Feb 21, 2023
Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices	Sep 14, 2018
Electromagnetic Compatibility (EMC) of Medical Devices	June 6, 2022
Performance Standards for CT Equipment and Laser Products (21 CFR 1020.33 and 21 CFR 1040.10)	—
Use of International Standard ISO 10993-1	Sep 8, 2023

Verification and Validation

Detailed verification and validation (V&V) results are provided in the full system and sub-system reports included in this submission. Verification and validation activities, including software verification, risk management, and design validation, demonstrate that the proposed CT Rembra

RT, CT Areta RT, and CT Rembra meet design input requirements and perform as intended for their clinical workflow and intended use.

Additional Non-Clinical Performance Testing

Additional non-clinical performance testing was conducted to support new and modified features, including pulmonary gating (4D CT), extended field of view (EFOV), body perfusion, MM Sim auto-launch, OnPlan, and CANOpen injection.

These evaluations included phantom testing, system verification and validation, and external image quality assessment, as applicable, and demonstrated acceptable performance for the intended use.

Bench Testing Summary

Table 4. Summary of Non-Clinical Performance Testing

Feature	Testing Performed	Summary of Results
Pulmonary Gating (4D CT)	Phantom testing, system V&V, external image quality review	Demonstrated acceptable image quality and reduced motion artifacts for intended use
Extended Field of View (EFOV)	Phantom testing, system V&V, external image quality review	Demonstrated acceptable geometric and quantitative accuracy for RT planning applications
Body Perfusion, MM Sim auto-launch, OnPlan	System V&V	Demonstrated acceptable performance for intended use
CANOpen Injection	Subsystem and system V&V	Demonstrated acceptable performance for intended use

The non-clinical performance testing supports the determination of substantial equivalence and demonstrates that the proposed CT Rembra RT, CT Areta RT, and CT Rembra:

- Comply with applicable standards and guidance; and
- Meet predefined acceptance criteria for their intended use.

The proposed devices did not require clinical studies, as substantial equivalence to the predicate devices CT5300 (K232491), Philips CT Big Bore (K171850), and Spectral CT 7500 RT (K240844) was demonstrated based on:

- Indications for use;
- Technological characteristics; and
- Non-clinical performance testing.

Differences in technological characteristics are supported by non-clinical performance data and do not raise new questions of safety and effectiveness. These results support a determination that the proposed CT Rembra RT, CT Areta RT, and CT Rembra are substantially equivalent to the predicate devices.

Cybersecurity

Cybersecurity risk management and testing were conducted in accordance with applicable FDA guidance, including *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

A risk-based approach was applied to identify potential cybersecurity threats and vulnerabilities. Appropriate risk control measures were implemented and verified through system and sub-system level testing, including vulnerability assessment and testing.

Cybersecurity verification and validation activities demonstrate that the proposed devices are designed to protect against unauthorized access and maintain the confidentiality, integrity, and availability of system data. These activities support that the proposed devices do not raise new questions of safety and effectiveness and support a determination of substantial equivalence.

Conclusions

The non-clinical data support the substantial equivalence of the proposed devices. Hardware and software verification and validation demonstrate that the CT Rembra RT, CT Areta RT, and CT Rembra perform as intended in the specified use conditions. The data included in this submission demonstrate that the proposed devices are as safe and effective as the predicate devices and support a determination of substantial equivalence.