May 3, 2024

Philips Healthcare (Suzhou) Co., Ltd.
℅ An Shiguang
Regulatory Affairs Manager
No. 258, Zhongyuan Road, Suzhou Industrial Park
SUZHOU JIANGSU, CHINA, 215024

Re: K232491
Trade/Device Name: CT 5300
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 4, 2024
Received: April 4, 2024

Dear An Shiguang:

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.

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
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)*
K232491

Device Name
CT 5300

Indications for Use *(Describe)*
The CT 5300 is a 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 supports, components and accessories. The CT 5300 is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in 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 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.

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92(c)]

Date Prepared:	Mar 8, 2024	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, Zhongyuan Road, Suzhou Industrial Park, Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630 Additional Manufacturing Site: Philips Medical Systems Technologies, LTD. Advanced Technology Center MATAM, Building 34, 3100202 Haifa Israel. Establishment Registration Number: 9617978	
Primary Contact Person: **Secondary Contact Person**	Shiguang An Regulatory Affairs Engineer Phone: +86-0-13940106467 E-mail: shiguang.an@philips.com Erhong Wang Senior Manager Regulatory Affairs Phone : +86-0-13021019589 E-mail : erhong.wang@philips.com	
Device Name:	CT 5300	
Classification:	Classification name:	Computed tomography x-ray system
	Classification Regulation:	21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	JAK
Primary Predicate Device:	Trade name:	Philips Incisive CT
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K212441
	Classification Regulation:	21CFR 892.1750
	Classification name:	Computed tomography x-ray system
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	JAK

Device Description:	The proposed device 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. This system also includes signal analysis and display equipment, patient and equipment supports, components, and accessories. The CT 5300 has a 72 cm bore and includes a detector array that provides 50 cm scan field of view (FOV). The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the proposed device have the same fundamental design characteristics and are based on comparable technologies as the current marketed predicate Philips Incisive CT K212441(April 27, 2022). The key system modules and functionalities are: 1. Gantry The Gantry consists of 4 main internal units: a. X-Ray Tube – produces X-rays necessary for scanning. b. High voltage generator - produces high voltage power supply to X-ray tube, consists of system Interface Unit, Power Block Unit and Anode Drive Unit. c. A-plane: adjusts the slice thickness during axial scan and monitor the changes of X-ray. d. DMS (Data Management System) – absorbs X-ray radiation by detectors and converts it to digital readout. 2. Patient Table (Couch) The Couch is used to position the patient. Carries the patient in and out through the Gantry bore synchronized with the scan. 3. Console The console is used to operate the system and monitor the scan. The Operator console includes a computer, monitors and CTBOX. 4. CT on Trailer Kit The CT 5300 installed and secured on a trailer requires locking motion parts during trailer transportation and unlocking motion parts before CT operations. Besides being installed in hospital, the CT may also be installed on trailer to be transported to designated locations for use within a professional healthcare environment.

	The CT 5300 on Trailer Kit has the same fundamental design characteristics and technologies as the current marketed Philips Incisive CT on trailer (K211168 - November 22, 2021). The CT on Trailer configuration is identical to the K211168 trailer configuration. The CT system should only be used in designated locations for use with appropriate radiation controls and safety measures. In addition to the above components and the software operating them, each system 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. Upgrades Kit is available to upgrade earlier Incisive CT installations to latest version.
Indications for Use:	The CT 5300 is a 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 supports, components and accessories. The CT 5300 is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in 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 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.

Fundamental Scientific Technology:	The proposed device is an advanced continuous rotation computed tomography system suitable for a wide range of computed tomographic (CT) applications. The proposed device is used clinically as a diagnostic patient imaging device that produces images that correspond 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 principal technological components (rotating x-ray tube, detector and gantry) of the proposed device are substantially equivalent to the currently marketed predicate device Philips Incisive CT (K212441 (April 27, 2022). Based on the information provided above, the proposed device does not raise different questions of safety and effectiveness compared to the currently marketed predicate device Philips Incisive CT (K212441(April 27, 2022).

Summary of Non-Clinical Performance Data:	The proposed device conforms to international standards, FDA-recognized consensus standards, 21 CFR Subchapter-J performance standards, NEMA industry standards, and FDA guidance documents. • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R) 2012 (Consolidated Text) [Incl. AMD2:2021] Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD) [Incl. AMD2:2021]. FDA/CDRH recognition number 19-46 • IEC 60601-1-2:2020 (Consolidated Text) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances – Requirements and tests FDA/CDRH recognition number 19-36 • IEC 60601-1-3:2021(Consolidated Text) Medical electrical equipment -- Part 1-3: General requirements for basic safety - Collateral standard: Radiation protection in diagnostic X-ray equipment FDA/CDRH recognition number 12-336 • IEC 60601-1-6:2020(Consolidated Text) Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability FDA/CDRH recognition number 5-132 • IEC 60601-2-44:2016 Medical electrical equipment - Part 2-44: Particular requirements for the safety and essential performance of X-ray equipment for computed tomography FDA/CDRH recognition number 12-302 • IEC 62304:2015 (Consolidated Text) Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-79 •IEC 62366-1:2020 Medical devices -- Part 1: Application of usability engineering to medical devices FDA/CDRH recognition number 5-129 • ISO14971:2019 Medical devices – Application of risk management to medical devices FDA/CDRH recognition number 5-125

	• ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process FDA/CDRH recognition number 2-258 • NEMA XR 25-2019 Computed Tomography Dose Check FDA/CDRH recognition number 12-325 • NEMA XR 26:2020 Access Controls for Computed Tomography: Identification, Interlocks, and Logs • NEMA XR 28-2018 Supplemental Requirements for User Information and System Function Related to Dose in CT FDA/CDRH recognition number 12-330 • NEMA XR 29-2013 Standard Attributes on CT Equipment Related to Dose Optimization and Management • Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Device Software functions (Issued June 14, 2023, document number GUI00000337). • Guidance for Industry and FDA Staff – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023, document number GUI00001825) • Guidance for Industry and FDA Staff – Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued September 4, 2020, document number 1811-R1) • Guidance for Industry and Food and Drug Administration Staff – Electromagnetic Compatibility (EMC) of Medical Devices: (issued June 6, 2022, document number 1400057) • Performance standards for Computed Tomography (CT) Equipment and Laser products (21 CFR 1020.33 and 21 CFR 1040.10, respectively).

	Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results. Non- Clinical verification and or validation test results demonstrate that the proposed device: • Complies with the aforementioned international standards, FDA-recognized consensus standards, Subchapter-J performance standards, NEMA industry standards and FDA guidance documents. • Meets the acceptance criteria and is adequate for its intended use. Precise Image (K210760) was modified for use in the CT 5300 system. With no changes to the algorithm architecture, new models were introduced to enable the reconstruction of a new organ type (cardiac), support more slice thickness and increment combinations, a new scan mode (high resolution head), and more clinical scenarios for body and head. All models were adequately trained and successfully compared using half-dose Precise Image reconstructions with full-dose iDose4 reconstructions. The comparative image quality assessment using phantoms demonstrated acceptable performance for the new models used in Precise Image. Additionally, a comparative image evaluation by two US Board Certified Radiologists of 126 image set pairs (including cases with pathology) comprising 31 unique patients representing the newly supported reconstructions. The comparative image assessment demonstrated that half-dose images processed by Precise Image in CT 5300, including both new and original existing models, are of equal or greater diagnostic quality compared to full dose images processed by iDose4. The comparative external image assessment confirms the validity of successful bench testing and clinical image quality evaluations, and when taken together, demonstrate Precise Image in CT 5300 to be as safe and effective as the predicate, and thus substantially equivalent to Precise Image (K210760) in predicate Incisive CT (K212441). Precise Position (originally cleared in K203514) was modified for use in the CT 5300 with no change to the

	design of the AI algorithm, the body joints detection algorithm including CNN architecture, model parameters, inference pipeline, pre- and post-processing is same as what is used in the predicate Incisive CT. The original model was trained using a broad dataset and performance data using clinical images demonstrate the model can further support more exams (cardiac, spine, runoff). Evaluation/assessment of the modified Precise Position algorithm, system level verification and validation activities have been properly carried out to demonstrate it is as safe and effective as the predicate to process the newly integrated exams (cardiac, spine, runoff), hence the modified Precise Position in the CT 5300 is substantially equivalent to the predicate Incisive CT (K212441), which integrates Precise Position (originally cleared in K203514). Therefore, the proposed device is substantially equivalent to the primary currently marketed and predicate device Predicate Philips Incisive CT (K212441(April 27, 2022) in terms of safety and effectiveness.
Summary of Clinical Data:	The proposed device did not require clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing, bench testing, retrospective clinical data, and other evidence as outlined

Substantial Equivalence

Substantial equivalence is established through comparison of features and functions of the proposed CT 5300 device and predicate Philips Incisive CT (K212441).

Scan Characteristics Comparison			
	Proposed CT 5300 device	**Predicate Philips Incisive CT (K212441)**	**Conclusion**
No. of Slices	64/128	64/128	Identical. Therefore, substantially equivalent.
Scan Modes	Surview Axial Scan Helical Scan	Surview Axial Scan Helical Scan	Identical. Therefore, substantially equivalent.
Minimum Scan Time	0.35 sec for 360° rotation	0.35 sec for 360° rotation	Identical. Therefore, substantially equivalent.
Image (Spatial) Resolution	High resolution mode: 16 lp/cm Standard resolution mode: 13 lp/cm	High resolution mode: 16 lp/cm Standard resolution mode: 13 lp/cm	Identical. Therefore, substantially equivalent.
Image Noise	0.27% at 120 kV, 230 mAs, 10 mm slice thickness	0.27% at 120 kV, 230 mAs, 10 mm slice thickness	Identical. Therefore, substantially equivalent.
Slice Thicknesses	Helical: 0.67mm – 5mm Axial: 0.625 mm – 10.0mm	Helical: 0.67mm – 5mm Axial: 0.625 mm – 10.0mm	Identical. Therefore, substantially equivalent.
Scan Field of View	Up to 500 mm	Up to 500 mm	Identical. Therefore, substantially equivalent.
Image Matrix	Up to 1024 * 1024	Up to 1024 * 1024	Identical. Therefore, substantially equivalent.
Display	1920 * 1080	1920 * 1080	Identical.

			Therefore, substantially equivalent.
Host Infrastructure	Windows 10	Windows 10	Identical. Therefore, substantially equivalent.
Communication	Compliance with DICOM	Compliance with DICOM	Identical. Therefore, substantially equivalent.
Dose Reporting and Management	Compliance with NEMA XR25, XR26, XR28 and XR29	Compliance with NEMA XR25, XR28 and XR29	Compliance with more NEMA standard. Safety and effectiveness are not affected. Therefore, demonstrating substantial equivalence.

Software or Imaging Features Comparison			
CT 5300 Features Name	**Feature description**	**Same feature cleared in Predicate Philips Incisive CT (K212441)**	**Conclusion (Function/ User interface/ Workflow)**
2D Viewer	In 2D Viewer mode operator can review original axial images as acquired by the scanner.	Yes	Identical. Therefore, substantially equivalent.
MPR	Use the MPR mode to view three-plane orthogonal images. In this mode, the three shown planes can be easily correlated. Three orthogonal cut planes are shown: • Axial Orientation • Coronal Orientation • Sagittal Orientation	Yes	Identical. Therefore, substantially equivalent.
3D (volume mode)	The volume mode is used to display CT scanner data in a full volume image. It provides basic tools for image editing and generation of cine movies.	Yes	Identical.

			Therefore, substantially equivalent.
Virtual Endoscopy (Endo)	The CT Endo viewer is a review function that allows you to perform a general flythrough of any suitable anatomical structure that is filled with air or with contrast material, including general vessels, cardiac vessels, the bronchus, and the colon.	Yes	Identical. Therefore, substantially equivalent.
Image matrix	The Image Matrix parameter sets the number of pixels that the reconstructed image will contain. Select 512, 768, or 1024.	Yes	Identical. Therefore, substantially equivalent.
O-MAR	O-MAR stands for orthopedic metal artifact reduction. This post processing capability reduces metal induced artifacts and is directed for large orthopedics metals that cause photon starvation of the rays that pass through the metal object.	Yes	Identical. Therefore, substantially equivalent.
DoseRight Index (DRI)	DoseRight Index (DRI) is according to the current scan site and body size of the patient, the mAs suitable for the patient is automatically recommended, so that the image quality can meet the requirements of the diagnosis, and the radiation dose of the patient can be reduced as far as possible.	Yes	Identical. Therefore, substantially equivalent.
DOM	DOM combines angular and longitudinal information to modulate dose in three dimensions. Personalizes dose for each patient by automatically suggesting tube current settings according to the estimated patient diameter in the scan region. Angular dose modulation varies the tube current during helical scans according to changes in patient shape (eccentricity) and tissue attenuation as the tube rotates.	Yes	Identical. Therefore, substantially equivalent.
Precise Planning	Precise Planning can automatically adjust the scan range of subsequent Axial or Helical scan series, based on the Surview Image.	Yes	Identical. Therefore, substantially equivalent.
Oblique MPR	Support the adjustment of sagittal / coronal image construction in the planned scanning phase, and finally obtain the adjusted tilted multiplane image. On the basis of Insert MPR, surface reconstruction is carried out by interpolation of axial image and corresponding tilted image is generated.	Yes (It is called "Insert MPR" in predicate device)	Revised feature, on the basis of the cleared "Insert MPR", added the ability for users to tilt the MPR image. Safety and effectiveness are not affected.

			Therefore, substantially equivalent.
OnPlan	OnPlan is a gantry operational touch panel located on both sides of the gantry. The OnPlan gantry controls are used to activate the laser marker, controls patient table movements, display patient information and images, and conduct a new patient exam.	Yes	Identical. Therefore, substantially equivalent.
Precise Spine	Precise Spine application enables the system to assist the user to identify the lumbar disk space automatically and create a batch based on the protocol selected.	Yes	Identical. Therefore, substantially equivalent.
Precise Brain	Precise Brain application for a series of brain tissue slices that are parallel or vertical in the plane of the cranial CT scan.	Yes	Identical. Therefore, substantially equivalent.
Bolus Tracking	The Bolus tracking function maximizes the efficiency of CT scans that are enhanced through the use of a contrast agent. This is done by preceding the Clinical scan with Locator and Tracker scans.	Yes	Identical. Therefore, substantially equivalent.
SAS (Spiral Auto Start)	This feature enables the usage of the injector scan trigger.	Yes	Identical. Therefore, substantially equivalent.
Filming	The Filming application is used for viewing, rearranging, windowing and zooming images prior to sending them to be printed.	Yes	Identical. Therefore, substantially equivalent.
Worklist	The Worklist displays patient information provided by the HIS/RIS.	Yes	Identical. Therefore, substantially equivalent.
MPPS	If the patient is from the Worklist and the MPPS function is enabled, feedback regarding the study status of the patient can be sent to the hospital HIS/RIS.	Yes	Identical. Therefore, substantially equivalent.
Reporting	The Reporting package allows you to create customized reports using pre-formatted templates. A template is a specially designed formatting document that places the analytical information and images that you send from an application into an organized report which can be printed and saved.	Yes	Identical. Therefore, substantially equivalent.
CCT (Continuous CT)	Continuous CT (CCT) is a scanning mode that allows the physician to perform	Yes	Identical.

	extended, low-dose scans while performing a biopsy. The resulting images are displayed on a remote monitor in the scan room, providing visual feedback during the biopsy.		Therefore, substantially equivalent.
Brain Perfusion	Brain Perfusion is a blood flow imaging application that analyzes the uptake of injected contrast in order to determine perfusion-related information about one or more regions of interest.	Yes	Identical. Therefore, substantially equivalent.
Dental (Dental planning)	Dental applications are used to create true-size (life size) film images of the mandible and maxilla for assisting oral surgeons in planning implantation of prostheses. Using a special dental planning procedure, the images will be created from this scan which can be input into the Dental planning application.	Yes	Identical. Therefore, substantially equivalent.
iDose^4	iDose^4 is an iterative reconstruction technique that improves image quality through artifact prevention and increased spatial resolution at low dose.	Yes	Identical. Therefore, substantially equivalent.
Helical Retrospectiv -e Tagging	Helical retrospective cardiac scanning enables the system to acquire a volume of data while the patient's ECG is recorded. The acquired data is tagged and reconstructed retrospectively at any desired phase of the cardiac cycle.	Yes	Identical. Therefore, substantially equivalent.
Axial Prospective Gating calcium scoring	Axial prospective gating uses an external ECG gating system to synchronize individual axial scans with the patient's heartbeat. The ECG-triggered scans significantly minimize heart-motion artifacts.	Yes	Identical. Therefore, substantially equivalent.
Step & Shoot	Step & Shoot Cardiac provides high quality CT images of the coronary arteries and heart anatomy at very low radiation dose levels. During Step & Shoot Cardiac, X-rays are generated only during the cardiac phase of interest.	Yes	Identical. Therefore, substantially equivalent.
CCS (Cardiac calcium scoring)	The Cardiac Calcium Scoring application is used to quantify the buildup of calcium plaque on the walls of the patient's coronary arteries and other relevant locations. The potential calcifications are highlighted by the application during launch.	Yes	Identical. Therefore, substantially equivalent.
Precise image	Precise image reconstruction is a recon mode where the system uses a trained deep learning neural network to generate noise reduction images compared with standard FBP recon mode for adult patients only. Precise Image has not been	Yes	Same AI/ML image recon algorithm, modified with new models to enable the reconstruction

	validated for lung cancer screening indications.		of a new organ type (cardiac), support more slice thicknesses, a new scan mode (high resolution head), and more clinical scenarios for body and head. No change to algorithm architecture compared to predicate device, therefore, substantially equivalent.
Precise cardiac	Precise Cardiac is a reconstruction technique with the potential to provide compensation for cardiac motion.	Yes	Identical. Therefore, substantially equivalent.
Precise position	Precise Position is a camera-based workflow designed to assist with positioning the patients aged 16 years and older automatically from console or OnPlan, it can: • automatically select patient orientation. • automatically set vertical centering & positioning of the patient to the Surview start and end positions. • support editing Surview start & end range and scan direction.	Yes	Same AI/ML algorithm, modified to support more exams (cardiac, spine, runoff). No change to algorithm architecture compared to predicate device, therefore, substantially equivalent.
Precise intervention	In Precise Intervention viewer there are several tools, they will help you to navigate the needle safely during the intervention.	Yes	Same interventional feature as predicate device. To duplicate one additional Interventional controls panel from couch side to a mobile cart for convenience. There is no change to SW algorithm

			compared to predicate device. Therefore, substantially equivalent.
Direct results	Direct Result-With Direct Result the user is able to choose a desired result during scan planning phase and get the result for diagnosis without further intervention.	Yes	Identical. Therefore, substantially equivalent.
Parallel workflow	The system support Parallel workflow using Dual monitor as below: - main monitor: Patients, scan, service, "show all" for scan planning, Help. - extend monitor: Completed, viewers, Analysis, recon, filming, report	Yes	Identical. Therefore, substantially equivalent.
CTC (CT Colonoscopy)	CT Colonoscopy (CTC) application enables fast and easy visualization of colon scans, using acquired CT images.	Yes	Identical. Therefore, substantially equivalent.
VA (Vessel Analysis)	Vessel Analysis (VA) offers a set of tools for general vascular analysis. With VA the user can easily remove bone, and extract vessels. Users also can perform measurements such as intraluminal diameter, cross-sectional lumen area, length.	Yes	Identical. Therefore, substantially equivalent.
LNA (Lung Nodule Analysis)	The Lung Nodule Analysis (LNA) application assists the radiologist with the detection and quantification of pulmonary nodules and lesions.	Yes	Identical. Therefore, substantially equivalent.
CAA (Cardiac Artery Analysis)	The Coronary Artery Analysis provides viewing and measuring tools that allow you to perform dimensional and quantitative measurements of the coronary arteries to help you identify and examine the patient study for stenosis.	Yes	Identical. Therefore, substantially equivalent.
CFA (Cardiac Function Analysis)	Cardiac Function Analysis (CFA) application is used to assess the state of the left ventricle (LV) and to analyze functional heart data.	Yes	Identical. Therefore, substantially equivalent.
Dual Energy	Dual energy Viewer is an application for review and analysis of CT dual-energy scans. Users need to load CT dual-energy scan data which is two series with similar KV. It provides registration function and can generate different	Yes	Identical. Therefore, substantially equivalent.

	weighted KV images. Users can use the tools to separate materials.		
Substantial Equivalence Conclusion:	The CT 5300 system design, intended use, technology and principal technological components (Tube, Generator, Detector) of the proposed device are substantially equivalent to the currently marketed predicate device Philips Incisive CT (K212441 - April 27, 2021). Based on the information provided above, the proposed device with modifications does not raise new questions of safety and effectiveness compared to the currently marketed predicate device Philips Incisive CT (K212441 - April 27, 2022).		