February 8, 2023

Philips Healthcare (Suzhou) Co., Ltd
% Diana Xu
Associated Regulatory Affairs Manager
No.258, ZhongYuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K223311
Trade/Device Name: Philips CT 3500
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK

Dear Diana Xu:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 22nd, 2023. Specifically, FDA is updating this SE Letter as an administrative correction because there was an inadvertent formatting error in the page header.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lu Jiang, OHT8: Office of In Vitro Diagnostics, (240) 402-5779, Lu.Jiang@fda.hhs.gov.

Sincerely,

Lu Jiang 2023.02.08 10:03:27 -05'00'

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

December 22, 2022

Philips Healthcare (Suzhou) Co., Ltd
% Diana Xu
Associated Regulatory Affairs Manager
No.258, ZhongYuan Road, Suzhou Industrial Park
Suzhou, Jiangsu 215024
CHINA

Re: K223311
Trade/Device Name: Philips CT 3500
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: October 27, 2022
Received: October 28, 2022

Dear Ms. Xu:

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,

Lu Jiang 2022.12.22 09:52:43 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223311

Device Name
Philips CT 3500

Indications for Use *(Describe)*

The Philips CT 3500 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 Philips CT 3500 is indicated for head, whole body, cardiac (Cardiac Calcium Scoring) 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.

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PRAStaff@fda.hhs.gov

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510(k) Summary of Safety and Effectiveness K223311
[As required by 21 CFR 807.92(c)]

Date Prepared:	October 26, 2022	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd. No. 258, Zhongyuan Road, Suzhou Industrial Park, Suzhou Jiangsu, CHINA, 215024 Establishment Registration Number: 3009529630	
Primary Contact Person: **Secondary Contact Person**	Diana Xu Associated Regulatory Affairs Manager Phone: +86-18940060508 E-mail: diana.xu@philips.com Erhong Wang Senior Manager Regulatory Affairs Phone: +86-512-67336804 E-mail: ErHong.WANG@philips.com	
Device Name:	Philips CT 3500	
Classification:	Classification name:	Computed tomography x-ray system
	Classification Regulation:	21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	JAK
Predicate Device:	Trade name:	Philips Incisive CT
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K212441, K211168
	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 **Philips CT 3500** 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 **Philips CT 3500** has a 72cm bore and includes a detector array that provides 50cm scan field of view (FOV). Besides installed in hospital, the proposed **Philips CT 3500** may also be installed on trailer and be transported to designed locations for use. And **Philips CT 3500** installed on trailer has the same intended use as installed in hospital. The key components that are used in the proposed **Philips CT 3500** have the same fundamental design characteristics and are based on comparable technologies as the current market predicate Philips Incisive CT (K212441 - April 27, 2022). CT on Trailer Kit that is used in the proposed **Philips CT 3500** to install and secure the CT system on trailers have the same fundamental design characteristics and are based on comparable technologies as the current market predicate Philips Incisive CT on trailer (K211168 - November 22, 2021). Trailers are provided by trailer manufactures and are not components of the proposed **Philips CT 3500**. The key system modules and functionalities are: 1. Gantry. The Gantry consists of 4 main internal units: a) X-Ray Tube – produce X-ray necessary for scanning. b) High voltage generator - produce high voltage power supply to X-ray tube, consists of system Interface Unit, Power Block Unit and Anode Drive Unit. c) A-plane: adjust the slice thickness during axial scan and monitors the changes of X-ray d) DMS (Data Measurement System) – absorb X-ray radiation by detectors and convert it to digital readout. 2. Patient Table (Couch)

	Couch is used to position the patient. Carries the patient in and out through the Gantry bore synchronized with the scan. 3. Console It is used to operate the system and monitor the scan. The Operator console includes computer, monitor and CTBOX. 4. CT on Trailer Kit **Philips CT 3500** installed and secured on trailer requires locking motion parts during trailer transportation and unlocking motion parts before CT operations. CT on Trailer Kit is used to install and secure the CT system on trailers, trailers are provided by trailer manufactures and are not components of the proposed **Philips CT 3500**. 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.
Indications for Use:	The Philips CT 3500 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 Philips CT 3500 is indicated for head, whole body, cardiac (Cardiac Calcium Scoring) 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 **Philips CT 3500** is advanced continuous rotation computed tomography systems suitable for a wide range of computed tomographic (CT) applications. The proposed **Philips CT 3500** 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 imaging chain components (x-ray tube, high voltage generator and detector) of the proposed **Philips CT 3500** substantially equivalent to the currently marketed predicate device Philips (K212441 -April 27, 2022; K211168 - November 22, 2021). Based on the information provided above, the proposed **Philips CT 3500** does not raise different questions of safety and effectiveness compared to the currently marketed predicate device (K212441 -April 27, 2022; K211168 - November 22, 2021).

Summary of Non-Clinical Performance Data:	The proposed **Philips CT 3500** comply with the following international and FDA-recognized consensus standards: • AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD). FDA/CDRH recognition number 19-4 • IEC 60601-1-2 Edition 4.0 2014-02, 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 19-8 • IEC 60601-1-3 Edition 2.1 2013-04, Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment FDA/CDRH recognition number 12-269 • IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION, 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 Edition 3.2: 2016, Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography FDA/CDRH recognition number 12-302 • IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-79 • IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices -- Part 1: Application of usability engineering to medical devices FDA/CDRH recognition number 5-129

	• ISO 14971 Third Edition 2019-12 Medical devices – Application of risk management to medical devices FDA/CDRH recognition number 5-125 • ISO 10993-1 Fifth edition 2018-08 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 28-2013 Supplemental Requirements for User Information and System Function Related to Dose in CT FDA/CDRH recognition number 12-287 • 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 Software Contained in Medical Devices (issued May 11, 2005, document number 337) • Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014, document number 1825) • 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)

	The systems comply with industry guidance and performance standards for Computed Tomography (CT) Equipment and Laser products (21 CFR 1020.33 and 21 CFR 1040.10, respectively). The systems performed a comparison to the predicate device using these technological characteristics and image quality metrics to establish that the subject device is substantially equivalent to the predicate device for its intended use. The systems pass the design verification, design validation and consensus standards test as nonclinical tests. The system verification is conducted against the system requirement specifications (SRS). System verification activities demonstrate the system meet the established system design input requirements. System requirements may be verified by manual test, automated test, inspection/analysis, or any combination of the three. Non-Clinical design validation testing covered the intended use and commercial claims. Validation testing included workflow validation. The test results demonstrate that the proposed **Philips CT 3500** meets the acceptance criteria and is adequate for its intended use. Additionally, the risk management activities show that all risks are sufficiently mitigated, that no new risks are introduced, and that the overall residual risks are acceptable.
Summary of Clinical Data:	The proposed **Philips CT 3500** did not require clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.

Substantial Equivalence

Installed Environment Comparison			
	Proposed Philips CT 3500	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion**
Installed environment	In hospital, on trailer	In hospital, on trailer	Identical. Therefore, substantially equivalent.
CT on Trailer	Besides installed in hospital, the proposed Philips CT 3500 may also be installed on trailer and be transported to designated locations for use. And Philips CT 3500 installed on trailer has the same intended use as installed in hospital. The design, intended use, fundamental scientific technology and principal technological components (Tube, Generator, Detector, gantry, patient table and console) are same as the proposed Philips CT 3500 in hospital except for the addition of a CT on Trailer Kit to secure the CT system in a trailer. CT on Trailer Kit includes: • Couch vertical lock and horizontal lock ASSY, • UPS lock ASSY, • Console lock ASSY,	Besides installed in hospital, the proposed Philips Incisive CT may also be installed on trailer and be transported to designated locations for use. And Incisive CT installed on trailer has the same intended use as installed in hospital. The design, intended use, fundamental scientific technology and principal technological components (Tube, Generator, Detector, gantry, patient table and console) are same as the Philips Incisive CT in hospital except for the addition of a CT on Trailer Kit to secure the CT system in a trailer. CT on Trailer Kit includes: • Gantry tilt lock ASSY, • Couch vertical lock ASSY, • Couch horizontal lock ASSY,	The proposed Philips CT 3500 Gantry has no tilt function. All motion parts can be fixed by on trailer kit. The design, intended use, fundamental scientific technology and principal technological components are identical to the predicate device. Safety and effectiveness are not affected. Therefore, demonstrating substantial equivalence.

Installed Environment Comparison			
	Proposed Philips CT 3500	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion**
	• Isolation Transformer lock ASSY	• UPS lock Kits, • Console fixation device, • Isolation Transformer lock Kits	

Scan characteristics Comparison			
	Proposed Philips CT 3500	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion**
No. of Slices	32/64	64/128	The Philips CT 3500 uses the same DMS (20mm) as the Philips Incisive CT to support 64 slices. Therefore, demonstrating Substantial equivalence.
Scan Modes	Surview Axial Scan Helical Scan	Surview Axial Scan Helical Scan	Identical. Therefore, substantially equivalent.
Minimum Scan Time	0.5 sec for 360° rotation	0.35 sec for 360° rotation	The proposed Philips CT 3500 rotation speed lower than Philips Incisive CT. Safety and effectiveness are not affected.

Scan characteristics Comparison			
	Proposed Philips CT 3500	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion**
			Therefore, demonstrating substantial equivalence.
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	≤0.18% at 120kV, $CTDI_{center}$ (head) ≤ 33mGy, 10mm image thickness, iDose[4]	≤0.18% at 120kV, $CTDI_{center}$ (head) ≤ 33mGy, 10mm image thickness, iDose[4]	Identical. Therefore, substantially equivalent.
Slice Thicknesses	Helical: 0.67mm – 5mm Axial: 0.625mm – 10.0mm	Helical: 0.67mm – 5mm Axial: 0.625mm-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.

Scan characteristics Comparison			
	Proposed Philips CT 3500	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion**
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, substantially equivalent.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**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	Yes	Identical. Therefore, substantially equivalent.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
	• Coronal Orientation • Sagittal Orientation		
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 Endoscope (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.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
3D-DOM	3D-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.	iPlanning	Only the name changes. Safety and effectiveness are not affected. 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.	Insert MPR	On the basis of Insert MPR, Added the ability for users to tilt the MPR image Safety and effectiveness are not affected. Therefore, substantially equivalent.
OnPlan	OnPlan (Touch Panel) OnPlan is a brand-new gantry operational touch panel located on both sides of the gantry. The OnPlan gantry controls are used to active the laser marker, controls patient table	iStation (Touch Panel)	Only the name changes. Safety and effectiveness are not affected.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
	movements, display patient information and images, and conduct a new patient exam.		Therefore, substantially equivalent.
Precise Spine	Precise Spine Precise Spine application enables the system to assist the user to identify the lumbar disk space automatically and creating a batch based on the protocol selected.	iBatch iBatch application enables the system to assist the user to identify the lumbar disk space automatically and creating a batch based on the protocol selected.	Only the name changes. Safety and effectiveness are not affected. 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.
Spiral Auto Start (SAS)	This feature enable 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	Yes	Identical.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
	study status of the patient can be sent to the hospital HIS/RIS.		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 extended, low-dose scans while performing a biopsy. The resulting images display on a remote monitor in the scan room, providing visual feedback during the biopsy.	Yes	Identical. 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 planning	Dental application uses 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, and the images will be created from this scan which	Yes	Identical. Therefore, substantially equivalent.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
	can be input into the Dental planning application.		
Axial Gating	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.
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.
Precise image	Precise image reconstruction is a recon mode where the system uses a trained deep learning neural network to generate noise reduction images and improve low contrast detectability with reduced dose compared with standard FBP recon mode.	Yes	Identical. Therefore, substantially equivalent.
Precise position	Precise Position is a camera-based workflow designed to assist with positioning the patient 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	Identical. Therefore, substantially equivalent.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
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.
CT Colonoscopy (CTC)	CT Colonoscopy (CTC) application enables fast and easy visualization of colon scans, using acquired CT images.	Yes	Identical. Therefore, substantially equivalent.
Vessel Analysis (VA)	Vessel Analysis (VA) offers a set of tools for general vascular analysis. With VA the user can easily remove bone, and extract vessels. User also can perform measurements such as intraluminal diameter, cross-sectional lumen area, length.	Yes	Identical. Therefore, substantially equivalent.
Lung Nodule Analysis (LNA)	The Lung Nodule Analysis (LNA) application assists the radiologist with the detection and quantification of pulmonary nodules and lesions.	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 weighted KV images. User can use the tools to separate materials.	Yes	Identical. 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	Identical. Therefore, substantially equivalent.

Imaging features Comparison			
Philips CT 3500 Features Name	**Feature description**	**Predicate Device Philips Incisive CT (K212441, K211168)**	**Conclusion (Function/ User interface/ Workflow)**
iDose[4]	iDose4 is an iterative reconstruction technique that improves image quality through artifact prevention and increased spatial resolution at low dose.	Yes	Identical. Therefore, substantially equivalent.
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.
Adaptive Filtering	Adaptive filters (AF) reduce pattern noise (streaks) in non-homogenous bodies, improving overall image quality.	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.

Substantial Equivalence Conclusion:	The design, intended use, technology, and principal technological imaging chain components (x-ray tube, high voltage generator and detector) of the proposed **Philips CT 3500** substantially equivalent to the currently marketed predicate device Philips Incisive CT (K212441 - April 27, 2022; K211168 - November 22, 2021). Based on the information provided above, the proposed **Philips CT 3500** does not raise different questions of safety and effectiveness compared to the currently marketed predicate device Philips Incisive CT (K212441 - April 27, 2022; K211168 - November 22, 2021). The proposed **Philips CT 3500** is identical to the predicate device Philips Incisive

	CT (K212441 - April 27, 2022; K211168 - November 22, 2021) and therefore is considered substantially equivalent. Additionally, substantial equivalence was demonstrated with non-clinical performance, V&V and consensus standards tests, which complied with the requirements specified in the international and FDA-recognized consensus standards. The results of these tests demonstrate that the proposed **Philips CT 3500** meets the acceptance criteria and is adequate for its intended use.