April 27, 2022

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

Re: K212441
Trade/Device Name: Philips Incisive CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: March 16, 2022
Received: March 16, 2022

Dear Shiguang An:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212441

Device Name
Philips Incisive CT

Indications for Use *(Describe)*

The Incisive CT 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 Incisive CT 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)

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PHILIPS

Traditional 510(k)

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92(c)]

Date Prepared:	July 30, 2021	
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**	Shiguang An Regulatory Affaires Engineer Phone: +86-24-28206367 E-mail: shiguang.an@philips.com Erhong Wang Senior Manager Regulatory Affairs Phone: +86-512-67336804 E-mail: ErHong.WANG@philips.com	
Device Name:	Philips Incisive CT	
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 Ingenuity CT
	Manufacturer:	Philips Medical Systems (Cleveland), Inc.
	510(k) Clearance:	K160743
	Classification Regulation:	21CFR 892.1750
	Classification name:	Computed tomography x-ray system
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	JAK
Secondary Predicate Device:	Trade name:	Philips Incisive CT
	Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.
	510(k) Clearance:	K180015
	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 Incisive CT** 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 Incisive CT** has a 72cm bore and includes a detector array that provides 50cm scan field of view (FOV). The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the proposed **Philips Incisive CT** have the same fundamental design characteristics and are based on comparable technologies as the current market predicate Philips Ingenuity CT (K160743, 08/08/2016). The main system modules and functionalities are: 1. Gantry. The Gantry consists of 4 main internal units: a. Stator – a fixed mechanical frame that carries HW and SW b. Rotor – A rotating circular stiff frame that is mounted in and supported by the stator. c. X-Ray Tube (XRT) and Generator,– fixed to the Rotor frame d. Data Measurement System (DMS) – a detectors array, fixed to the Rotor frame 2. Patient Support (Couch) – carries the patient in and out through the Gantry bore synchronized with the scan 3. Console - Containing a Host computer and display that is the primary user interface. 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. Patient supports (positioning aids) are used to position the patient.

Indications for Use:	The Incisive CT 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 Incisive CT 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 **Philips Incisive CT** is advanced continuous-rotation computed tomography systems suitable for a wide range of computed tomographic (CT) applications. The proposed **Philips Incisive CT** 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 **Philips Incisive CT** substantially equivalent to the currently marketed predicate device Philips Ingenuity CT (K160743, 08/08/2016) Based on the information provided above, the proposed **Philips Incisive CT** does not raise different questions of safety and effectiveness compare to the currently marketed predicate device Philips Ingenuity CT (K160743, 08/08/2016).

Summary of Non-Clinical Performance Data:	The proposed **Philips Incisive CT** 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 60601-1-2:2014, 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 60601-1-3:2013 Medical electrical equipment -- Part 1-3: General requirements for basic safety - Collateral standard: Radiation protection in diagnostic X-ray equipment FDA/CDRH recognition number 12-269 • IEC 60601-1-6:2013 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability FDA/CDRH recognition number 5-89 • 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 Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-79 • IEC 62366-1:2015, Medical devices -- Part 1: Application of usability engineering to medical devices FDA/CDRH recognition number 5-114 • ISO14971 Medical devices – Application of risk management to medical devices (Ed. 3.0, 2019) FDA/CDRH recognition number 5-125 • NEMA XR 25-2010 Computed Tomography Dose Check FDA/CDRH recognition number 12-225

	• 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) • 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 June 16, 2016) • Guidance for Industry and FDA Staff – Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (issued July 11, 2016) 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 using these technological characteristics and image quality metrics to establish that the subject device is substantially equivalent to the predicate 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 Incisive CT** 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 Incisive CT** did not require clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.

Substantial Equivalence

Scan characteristics Comparison			
	Proposed Philips Incisive CT	**Predicate Device Philips Ingenuity CT(K160743)**	**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	0.42 sec for 360° rotation	The proposed **Philips Incisive CT** rotation speed faster than Ingenuity CT to meet the wider heart rate application. Safety and effectiveness are not affected. 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	0.27% at 120 kV, 230 mAs, 10 mm slice thickness	0.27% at 120 kV, 250 mAs, 10 mm slice thickness	Identical. Therefore, substantially equivalent.
Slice Thicknesses	Helical: 0.67mm – 5mm Axial: 0.625mm – 10.0mm	Helical: 0.67mm – 5mm Axial: 0.625mm – 12.5mm	Essentially the same slice thickness, does not affect safety and effectiveness. Therefore, demonstrating substantial equivalence.
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	1024 * 1280	The proposed Philips Incisive CT provide higher resolution than Ingenuity CT. Safety and effectiveness are not affected. Therefore, demonstrating substantial equivalence.

Host Infrastructure	Windows 10	Windows 7	Same supplier, same technology and similar function. Therefore, substantially equivalent.
Communication	Compliance with DICOM	Compliance with DICOM	Identical. Therefore, substantially equivalent.
Dose Reporting and Management	Compliance with NEMA XR25 , XR28 and XR29	Compliance with NEMA XR25 and XR29	Compliance with more NEMA standard. Safety and effectiveness are not affected. Therefore, demonstrating substantial equivalence.

Imaging features Comparison			
Incisive CT Features Name	**Feature description**	**Secondary Predicate Device Philips Incisive CT(K180015)**	**Conclusion (Function/ User interface/ Workflow)**
2D Viewer	In 2D Viewer mode operator can review original axial images as acquired by the scanner.	Yes	Identical.
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.
3D(volume mode)	The volume mode is used to display CT scanner data in a full volume image. It	Yes	Identical.

	provides basic tools for image editing and generation of cine movies.		
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.
Filming	The Filming application is used for viewing, rearranging, windowing and zooming images prior to sending them to be printed.	Yes	Identical.
Image matrix	1024 * 1024	Yes	Identical.
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.
Dose Modulation	Dose-Modulation is a scanner function which modulates the tube current in two ways (angular and longitudinal modulation) simultaneously.	Yes	Identical.
Scan Preparation	iPlanning / Manual	Yes	Identical.
On line MPR	Use the on line MPR mode to view three-plane orthogonal images. In this mode, the three shown planes can be easily correlated.	Yes	Identical.
Control Panel	iStation (Touch Panel)	Yes	Identical.
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.	Yes	Identical.
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.
SAS(Spiral Auto Start)	This feature enable the usage of the injector scan trigger.	Yes	Identical.
Worklist	The Worklist displays patient information provided by the HIS/RIS.	Yes	Identical.
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.

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.
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.
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.
Dental (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 can be input into the Dental planning application.	Yes	Identical.
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.
Helical Retrospective 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.
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.

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.
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.
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.	**No**	Different: safety and effectiveness refer to K210760 for Precise Image
Precise cardiac	**Precise Cardiac** is a reconstruction technique with the potential to provide compensation for cardiac motion.	**No**	Different: safety and effectiveness refer to K203020 for Precise Cardiac
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.	**No**	Different: Safety and effectiveness refer to K203514 for Precise Position
Precise intervention	In **Precise Intervention** viewer there are several tools, they will help you to navigate the needle safely during the intervention.	**No**	Different: Precise intervention is a function that support user to view the distance, angle between the injector and the object, system validation report proved that

			there is no impact on system safety and effectiveness
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.	**No**	Different: Direct result is workflow enhancement to make user direct get derived image after acquisition no impact on system safety and effectiveness
Parallel workflow	**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	**No**	The Parallel workflow of Incisive CT is the workflow update, no impact safety and effectiveness.

Supplementary Imaging features Comparison			
Incisive CT Features Name	**Feature description**	**Secondary Predicate Device Philips Incisive CT(K180015)**	**Conclusion (Function/ User interface/ Workflow)**
CTC(CT Colonoscopy)	CT Colonoscopy (CTC) application enables fast and easy visualization of colon scans, using acquired CT images.	Yes	Identical.
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. User also can perform measurements such as intraluminal diameter, cross-sectional lumen area, length.	Yes	Identical.

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.
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.
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.
DE(Dual Energy)	Spin / Spin scan mode Dual energy Viewer is an application for review and analysis of CT dual-energy scans. User 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.

Substantial Equivalence Conclusion:	The design, intended use, technology and principal technological components (Tube, Generator, Detector) of the proposed **Philips Incisive CT** substantially equivalent to the currently marketed primary predicate device Philips Ingenuity CT (K160743, 08/08/2016).Based on the information provided above, the proposed **Philips Incisive CT** does not raise different questions of safety and effectiveness compare to the currently marketed primary predicate device Philips Ingenuity CT (K160743, 08/08/2016). The proposed **Philips Incisive CT** is identical to the primary predicate device Philips Ingenuity CT (K160743, 08/08/2016), 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 Incisive CT** meet the acceptance criteria and is adequate for its intended use.