November 22, 2021

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

Re: K211168
Trade/Device Name: Philips Incisive CT on Trailer
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 19, 2021
Received: October 19, 2021

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,

, for

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211168

Device Name
Philips Incisive CT on Trailer

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.

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.

*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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PHILIPS

510(k) Summary or Statement

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

Date Prepared:	March 30, 2021	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.	
	No. 258, ZhongYuan Road, Suzhou Industrial Park, 215024	
	Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA	
	Establishment Registration Number: 3009529630	
Contact Person:	Shiguang An	
	Advanced Regulatory Engineer	
	Phone cell: +86-139-40106467	
	Fax: +86-512-68018677 E-mail: shiguang.an@philips.com	
Device Name:	Philips Incisive CT on Trailer	
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:	K180015-March 20, 2018
	Classification Regulation:	21 CFR, Part 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 on Trailer** 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 support, components, and accessories. The Philips Incisive CT has a 72cm bore and includes a detector array that provides 50cm scan field of view (FOV). **Besides installed in hospital, Philips Incisive CT can also be installed on trailer and be transported to designated locations.** The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the proposed Philips Incisive CT on trailer are identical to the currently marketed and predicate Philips Incisive CT (K180015, 20/March/2018). The components of the proposed Philips Incisive CT on trailer include the following: 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. **4. CT on Trailer Kit - Modified Incisive CT installed and secured on trailer requires locking motion parts during trailer transportation and unlocking motion parts before CT operations.** 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. **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.** *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 on Trailer** is advanced continuous rotation computed tomography systems suitable for a wide range of computed tomographic (CT) applications. The proposed **Philips Incisive CT on Trailer** can be transported by the trailer to designated locations and 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, gantry, patient support and console) of the proposed Philips Incisive CT are identical to the currently marketed

	predicate device Philips Incisive CT (K180015, 20/March/2018). In addition, the Proposed **Philips Incisive CT on Trailer** provides CT on trailer kit which is used to install and secure Philips Incisive CT (K180015, 20/March/2018) on a trailer. Based on the information provided above, the proposed **Philips Incisive CT on Trailer** does not raise different questions of safety and effectiveness compare to the currently marketed predicate device Philips Incisive CT (K180015, 20/March/2018).
Summary of Non-Clinical Performance data:	The currently marketed **Philips Incisive CT** (K180015) complies 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 60601-2-44:2012 Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment FDA/CDRH recognition number 12-256 • IEC 62304:2015 Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-79 • IEC 62366:2014 Medical Device-Application of Usability Engineering of Medical Devices FDA/CDRH recognition number 5-87

	• ISO14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, 2007) FDA/CDRH recognition number 5-40 • 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) Additionally, the **Philips Incisive CT** complies with performance standards for Computed Tomography (CT) Equipment and Laser products (21 CFR 1020.33 and 21 CFR 1040.10, respectively). The proposed **Philips Incisive CT on Trailer** is identical to the currently marketed and predicate Philips Incisive CT (K180015) with regards to intended use, design and fundamental scientific technology except for trailer kit that is utilized to securely mount the CT system on the trailer. The trailer kit consists of locking mechanism that lock the gantry and couch parts of the CT System to the trailer. With regards to transportation testing the proposed **Philips Incisive CT on Trailer** complies with Department of Defense Test Method Standard for Environmental Engineering Considerations and Laboratory Tests (MIL-STD-810F), Method 514.5: Composite wheeled vehicle

	vibration exposures, as described in the main body, Annex A, Annex B and Annex C of this method. **Philips Incisive CT on Trailer** has passed the vibration test of 300 hours to simulate a 10 years or 120,690 kM lifetime with QA test including MeanCT, Uniformity, Noise, Spatial Resolution, Slice Thickness, Linearity and Low Contrast Resolution. The QA test process and acceptance criteria are same as the predicate device, this can demonstrate the **Philips Incisive CT on Trailer** performs as well as the predicate device.
Summary of Clinical Data:	Clinical data is not warranted to demonstrate safety and effectiveness of the proposed **Philips Incisive CT on Trailer** since its design, intended use and fundamental scientific technology is identical to the currently marketed and predicate Philips Incisive CT (K180015, 20/March/2018).
Substantial Equivalence Conclusion:	The design, intended use, fundamental scientific technology and principal technological components (Tube, Generator, Detector, gantry, patient support and console) of the proposed **Philips Incisive CT on Trailer** are identical to the currently marketed predicate **Philips Incisive CT** (K180015, 20/March/2018) except for the addition of a trailer Kit to secure the CT System in a trailer. Based on the information provided above, the proposed **Philips Incisive CT on Trailer** does not raise different questions of safety and effectiveness as compared to the currently marketed predicate Philips Incisive CT (K180015, 20/March/2018). The proposed Philips Incisive CT on Trailer is therefore substantially equivalent to the currently marketed and predicate Philips Incisive CT (K180015, 20/March/2018).