Philips Healthcare (Suzhou) Co., Ltd.
Ray Sun
Regulatory Affairs Engineer
No.258, ZhongYuan Road, Suzhou Industrial Park
SUZHOU, 215024 CHINA

July 29, 2019

Re: K191136
Trade/Device Name: Access CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: May 5, 2019
Received: May 7, 2019

Dear Ray Sun:

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 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)*

K191136

Device Name
Access CT

Indications for Use *(Describe)*

The Access CT scanner system can be used as a Whole Body (except cardiac) Computed Tomography X-ray System featuring a continuously rotating X-ray tube and detector array with multislice capability up to 6/16 slices simultaneously. The acquired X-ray transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.

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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510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92(c)]

Date Prepared:	March 5 2019	
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**	Ray Sun Regulatory Affair Engineer Phone: +86-13109886838 E-mail: wei.ws.sun@philips.com Shiguang An Regulatory Affair Engineer Phone: +86-13940106467 E-mail: shiguang.an@philips.com	
Device Name:	Access 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
Predicate Device:	Trade name:	PHILIPS MX 16 SLICE
	Manufacturer:	Philips Medical Systems (Cleveland), Inc.
	510(k) Clearance:	K091195
	Classification Regulation:	21CFR 892.1750
	Classification name:	Computed tomography x-ray system
	Classification Panel:	Radiology
	Device class	Class II
	Product Code:	JAK
Reference 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
Reference 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 **Access CT** is currently available in two system configurations, 6 slices and 16 slices. The Access CT system 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. When interpreted by a trained physician, CT images yield useful diagnostic information. The system is intended for use in the head and whole body. The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the **Access CT** have the same fundamental design characteristics and are based on comparable technologies as the predicate. 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 Access CT Scanner System can be used as a whole body (except cardiac) computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array with multi-slice capability up to 6/16 slices simultaneously. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from the same axial plane taken at different angles. The system is suitable for all patients.
Fundamental Scientific Technology:	The proposed **Access CT** is an advanced continuous-rotation computed tomography systems suitable for a wide range of computed tomographic (CT) applications. The proposed **Access 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 **Access CT** is substantially equivalent to the currently marketed predicate Philips MX 16 SLICE (K091195, 05/27/2009). Based on the information provided above, the proposed **Access CT** does not raise different questions of safety and effectiveness compare to the currently marketed predicate Philips MX 16 SLICE (K091195, 05/27/2009).
Summary of Non-Clinical Performance Data:	The proposed **Access CT** 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 60601-2-44:2016 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 62304:2006 Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-32 • 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. 2.0, 2007) FDA/CDRH recognition number 5-40 • NEMA XR 25-2011 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). Design Verification planning and testing was conducted at the sub-system and at the system level. The sub-systems are tested against the Sub-System Requirement Specifications (SSRSs) and the system level verification is conducted against the System Requirement Specification (SRS). System and sub-system verification activities demonstrate the system or sub-systems meet the established system and sub-system level design input requirements. System and sub-system level requirements may be verified by manual test, automated test, inspection/analysis, or any combination of the three. Design verification also includes Image Quality verification and risk analysis risk mitigation testing. Design validation of user needs and intended use was conducted via simulated use testing with production equivalent Access CT Systems. Validation testing included clinical workflow validation, service validation, and manufacturing validation. Conclusion: Traceability from requirements to test plans to test results confirmed, for both design verification and design validation, that design requirements were met. The Access CT System meets system design requirements and user needs and intended use.
Summary of Clinical Data:	The proposed Access CT System did not require any external clinical site testing. Clinical evaluation of workflow was conducted via simulated use testing and is accounted for in the Summary of Non-Clinical Testing section of the summary.

Substantial Equivalence

Table 5-1 Design/fundamental scientific technologies Comparison			
	Proposed Access CT	**Predicate Device Philips MX 16-slice(K091195)**	**Conclusion**
Application	Head/Body	Head/Body	Identical Substantially Equivalent
Scan Regime	Continuous Rotation	Continuous Rotation	Identical Substantially Equivalent
No. of Slices	6/16	16	Access CT 6 and Access CT 16 use the same Detector and other hardware configuration, by software control, 6 slices is implemented by combining different detecting units to achieve different slice thickness configuration. This does not affect the safety or effectiveness. Therefore, demonstrating substantial equivalence.
Scan Modes	Surview Axial Scan Helical Scan	Surview Axial Scan Helical Scan	Identical Substantially Equivalent
Minimum Scan Time	0.75 sec for 360° rotation	0.5 sec for 360° rotation	Increasing the Minimum scan time from 0.5 to 0.75 sec on the proposed Access CT does not affect the safety or effectiveness. Therefore, demonstrating substantial equivalence.
Image (Spatial) Resolution	High resolution mode : 15±10% lp/cm@0%	High resolution mode : 15 lp/cm	Identical Substantially Equivalent
Image Noise	≤0.35%	≤0.35%	Identical Substantially Equivalent
Image Matrix	512x512,	512x512,	Identical

	768x768, 1024x1024	768x768, 1024x1024	Substantially Equivalent
Display	1024 * 1280	1024 * 1280	Identical Substantially Equivalent
Host Infrastructure	Windows 7	Windows XP	Changing the Windows platform from Windows XP to Windows 7 does not affect the safety or effectiveness of the device. Therefore demonstrating substantial equivalence.
Communicatio n	Compliance with DICOM	Compliance with DICOM	Identical Substantially Equivalent
Dose Reporting and Management	Compliance with NEMA XR25, XR28 and XR29	none	Subject device compliant with NEMA standards. There is no impact on safety or effectiveness.
Generator and Tube			
Power (kW Output)	28 kW	50 kW	The difference of power output from 50 KW to 28KW does not have an impact on the functionality / performance and/or safety or effectiveness of the device. Therefore, demonstrating substantial equivalence.
mA Range	10mA-233mA	30mA-420mA	The impact of decreasing the tube power is an extended lower limit of mA range and decreased upper limit of mA range, difference in range does not affect safety or effectiveness. Therefore, demonstrating substantial equivalence.
kV Settings	70kV, 80kV, 100kV, 120kV, 140kV	90KV, 120KV and 140KV	The impact of decreasing the tube power is an extended kV range, difference in range does not

			affect safety or effectiveness. Therefore, demonstrating substantial equivalence.
Tube Type	CTR1735	CTR 2150 CEPN	Identical tube technology, and same tube supplier, does not affect safety or effectiveness. Therefore, demonstrating substantial equivalence.
Detectors			
Type	NanoPanel Elite	NanoPanel Elite	Identical Substantially Equivalent
Scan Field of View(SFOV)	450 mm	500 mm	The difference of SFOV impact on the scan field, does not affect safety or effectiveness. Therefore, substantially equivalent
Detector Type	Single layer ceramic scintillator plus a photodiode	Single layer ceramic scintillator plus a photodiode	Identical Substantially equivalent
Material	GOS solid	GOS solid	Identical Substantially equivalent
Gantry			
Tilt capability	There is no physical tilt on gantry. If the tilted images are requested by user, the digital tilt based images are created.	±30°	Both are available for axial scans. The difference does not affect safety or effectiveness. Therefore, substantially equivalent.
Gantry Rotation Speed	80 RPM	120 RPM	Identical transmission design with lower rotation speed Safety and effectiveness are not affected. Therefore, substantially equivalent.

Bore Size	650mm	700mm	Bore Size decreasing does not affect safety or effectiveness. Therefore, substantially equivalent.
Couch			
Maximum scannable range	Fixed height couch: ≤ 1200mm (with general head holder or foot extension) Vertical moveable couch: ≤1380mm(with general head holder or foot extension)	1,500 mm	Maximum scannable range decreasing does not affect safety or effectiveness. Therefore, substantially equivalent.
Z-position accuracy	+/- 0.25 mm	+/- 0.25 mm	Identical Substantially equivalent
Lowest table height	Fixed height couch: 815mm vertical movement couch: 480mm	579mm	The difference of table height does not affect safety or effectiveness. Therefore, substantially equivalent.
Maximum load capacity	Fixed height couch: 150kg vertical movement couch: 200kg	200kg	Both are compliant with IEC60601 series standards. The difference does not affect safety or effectiveness. Therefore, substantially equivalent.
Clinical Features			
2D Viewer	Yes	Yes	Identical Substantially equivalent
MPR	Yes	Yes	Identical Substantially equivalent
3D	Yes	Yes	Identical Substantially equivalent

VE(Virtual Endoscopy)	Yes	Yes	Identical Substantially equivalent
Filming	Yes	Yes	Identical Substantially equivalent
MAR	Yes	Yes	Identical Substantially equivalent
Dose Modulation	ACS,DOM	ACS,DOM	Identical Substantially equivalent
MPR	InsertMPR	InsertMPR	Identical Substantially equivalent
Bolus Tracking	Yes	Yes	Identical Substantially equivalent
SAS(Spiral Auto Start)	Yes	Yes	Identical Substantially equivalent
Worklist	Yes	Yes	Identical Substantially equivalent
MPPS	Yes	Yes	Identical Substantially equivalent
Reporting	Yes	Yes	Identical Substantially equivalent
CCT(Continuous CT)	Yes,	Yes	Identical Substantially equivalent
Brain Perfusion	Yes	Yes	Identical Substantially equivalent
Dental	Yes	Yes	Identical Substantially equivalent
VA(Vessel Analysis)	Yes	Yes	Identical Substantially equivalent

Table 5-2 shows that the proposed Access CT is considered substantially equivalent to the predicate Philips Ingenuity CT for the Iterative recon function, in terms of design/fundamental scientific technology.

Table 5-2 Design/fundamental scientific technologies Comparison			
	Proposed Access CT	**Reference Device Philips Ingenuity CT(K160743)**	**Conclusion**
Clinical Features			
Iterative recon	iDose^4	iDose^4	Identical
CTC(CT Colonoscopy)	Yes	Yes	Identical
LNA(Lung Nodule Analysis)	Yes	Yes	Identical

Table 5-3 shows that the proposed Access CT is considered substantially equivalent to the predicate Philips Incisive CT for the Clinical Features, in terms of design/fundamental scientific technology.

Table 5-3 Design/fundamental scientific technologies Comparison			
	Proposed Access CT	**Reference Device Philips Incisive CT(K180015)**	**Conclusion**
Clinical Features			
iPlanning	Yes	Yes	Identical
Batch image processing (iBatch)	Yes	Yes	Identical

Substantial Equivalence Conclusion:	The design, intended use, technology and principal technological components (Tube, Generator, Detector) of the proposed **Access CT** are substantially equivalent to the predicate PHILIPS MX 16 SLICE (K091195 -05/27/2009). Based on the information provided above, the proposed **Access CT** does not raise different questions of safety or effectiveness compared to the predicate PHILIPS MX 16 SLICE (K091195 - 05/27/2009). Therefore the proposed **Access CT** is considered substantially equivalent to the predicate PHILIPS MX 16 SLICE (K091195 - 05/27/2009). Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards. The results of these tests demonstrate that the proposed **Access CT** meet the acceptance criteria and is adequate for its intended use.