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

June 17, 2021

Re: K203514
Trade/Device Name: Precise Position
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 19, 2021
Received: May 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203514

Device Name

Precise Position

Indications for Use *(Describe)*

The Precise Position is intended for use with Philips Incisive CT systems. The device provides the following guided workflow.

- Patient orientation identification
- Surview range recommendation
- Automatic centering the patient anatomy
- Provide visual images of patient on the table

Precise position is indicated for use for CT imaging of the head, chest, abdomen, pelvis, and combination of those anatomies.

Patient population limitation: Patient younger than 16 years are not supported.

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

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

Date Prepared:	November 18, 2020	
Manufacturer:	Philips Healthcare (Suzhou) Co., Ltd.	
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	Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA	
	Establishment Registration Number: 3009529630	
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	E-mail: erhong.wang@philips.com	
Device Name:	**Precise position**	
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
Reference Device:	Manufacturer:	Auto Positioning

		GE Hangwei Medical System Co., Ltd.
	510(k) Clearance:	K192956 (January 16, 2020)
	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:	**Precise Position** is an optional feature to assist user for position the patient before the body examination such as CT scan. The purpose of this feature is to reduce the patient position time via the camera detection and calculation result. It includes automatic detect patient orientation, patient anatomy scan range and center of patient anatomy. **Precise Position** including a camera with both color and depth function is installed in the ceiling of the scan room, in such a way to cover the entire patient on the patient table. The camera control and image data transmit via the high speed fiber and copper hybrid USB cable. The power supply of the camera is from the gantry. Precise position adopts the AI algorithm (Convolution Neural Network) to detect the joints of the patient body, and then identify surview start/end position and patient orientation. The algorithm can also support detect center of patient anatomy. **Limitation for Precise Position** There is no limitation for Precise Position except below items: • Patients below the age of 16 are not supported. • Decubitus orientations are not supported. **The Precise Position display results may get affected by the following conditions:** • When the patient is covered by sheet, blanket etc., • When the patient is not completely covered by the ceiling camera view, e.g. blocked by the gantry or out of camera's FOV etc. • When the patient is wearing clothes that reflects light, e.g. plastic-like clothes. • When the patient is wearing black clothes. • When the patient is wearing thick clothes. • When there are other people around the patient.

Indications for Use:	The **Precise Position** is intended for use with Philips Incisive CT systems. The device provides the following guided workflow. • Patient orientation identification • Surview range recommendation • Automatic centering the patient anatomy • Provide visual images of patient on the table Precise position is indicated for use for CT imaging of the head, chest, abdomen, pelvis, and combination of those anatomies. Patient population limitation: Patient younger than 16 years are not supported.

<table>
<tr><td>Fundamental scientific technology:</td><td>Based on the information provided above, the precise position is considered substantially equivalent to the primary currently marketed and predicate device Philips Incisive CT (K180015, 20/March/2018) in terms of fundamental scientific technology.

<table>
<tr><td>Attribute</td><td>Predicate Device Philips Incisive CT (K180015)</td><td>Proposed Device Precise Position</td></tr>
<tr><td>Patient positioning workflow</td><td>Manually position the patient via the couch motion button and laser. Normally, need several round adjustments by user.</td><td>Precise position provides the auto workflow to set the surview start/end position, center of patient anatomy, and patient orientation.</td></tr>
<tr><td>Detection algorithm</td><td>The manual workflow does not need special algorithm.</td><td>Precise position adopt the AI algorithm (Convolution Neural Network) to detect the joints of the patient body automatically, and then automatic detect surview start/end position, center of patient anatomy and patient orientation.</td></tr>
<tr><td>Hardware need to support the patient positioning</td><td>Manual patient positioning does not need any unique hardware except traditional exiting hardware on the CT or other system. Exiting hardware includes table motion button (in/out, up/down) on gantry panel or CTBOX, lasers and etc.</td><td>Precision position feature need color and depth camera, high speed USB transmission cable, and power cable, and relative the enhanced workflow. The tradition exiting patient positioning hardware still be available for user all the time, it is convenient to switch between the camera automatically detecting mode and manual mode.</td></tr>
<tr><td>Patient population</td><td>All ages</td><td>More than 16 years old.</td></tr>
<tr><td>Environment of use</td><td>Hospitals, outpatient clinics, research institutions, and other clinical facilities.</td><td>Hospitals, outpatient clinics, research institutions, and other clinical facilities.</td></tr>
</table>
</td></tr>
<tr><td>Summary of Non-Clinical</td><td>The Precise Position complies with the following international and FDA-recognized consensus standards:</td></tr>
</table>

Performance data:	• 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 60601-1:2012, 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 • ISO 14971 Medical devices – Application of risk management to medical devices. FDA/CDRH recognition number 5-40. • IEC 62304:2015, Medical device software -- Software life cycle processes FDA/CDRH recognition number 13-79 There are no risks identified in risk management documentation that require clinical data for the purpose of clinical evaluation; Risk Management Plan as **Appendix 001**, Risk Management Report as **Appendix 002**, and Risk Management Matrix as **Appendix 003** of **Precise Position**. There are no clinical risks identified by the evaluated clinical data. Sufficient evidence is available to demonstrate the ability of **Precise Position** achieve the intended performances during normal condition of use. Full consistency exists between the state-of-the-art, the evaluated data, the risk management documentation and the information materials supplied. Therefore, the **Precise Position** is substantially equivalent to the primary currently marketed and predicate device (K180015, 20/March/2018) in terms of safety and effectiveness.
Summary of Clinical Data:	Precise Position is evaluation covered total 80 clinical scan positions in which 40 cases used with Precise Position and another 40 cases without the usage of Precise Position in order to meet the sample size calculation of 40 cases performed average on a CT scanner per day. The thorough clinical evaluation of this feature is done by 5 Clinical experts. The testing did not deliver radiation to volunteers as Precise Position is only for supporting the positioning of the patient for the localization radiograph and therefore “radiation” was not required for those volunteers.

	The clinical evaluation was done with 3 major objectives as follows, To calculate the time saved per surview planning with and without Precise Position. To calculate the accuracy of vertical (iso)center positioning and Surview (horizontal) start /end position with and without Precise Position Intra operator consistency in positioning the patient and surview scan range The summary of clinical evaluation testing was clearly demonstrating the objectives in terms of user benefits as shown below Average Time taken to position without Precise Position and with Precise Position is recorded. Time at user select the patient from Gantry Panel, to time when user pressed Go button from Gantry Panel is measured and concluded that up to 23% time reduction in patient positioning achieved with "Precise Positioning workflow". The average offset in mm for vertical (iso) center position among 5 operators without Precise Position and with Precise Position is recorded and results shown that with "Precise Position" the vertical position accuracy is increased up to 50%. Standard deviation in mm for vertical (iso)center positioning & Surview (horizontal) start position among 5 operators without Precise Position and with Precise Position is recorded and results shown up to 70% increase in Vertical and horizontal position consistency with Precise Position. Overall, the Precise Position Clinical Review Report. (Appendix_007) concluded that Philips Incisive CT systems with Precise Position, under normal condition of use, perform as intended, are safe for its intended use and have a favorable benefit-risk ratio. Further clinical investigations are not necessary, as sufficient evidence exists to support these conclusions.
Substantial Equivalence Conclusion:	The **Precise Position** is substantially equivalent to the primary currently marketed and predicate device (K180015, 20/March/2018) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304 and ISO 14971. The results of these tests demonstrate that **Precise Position** met the acceptance criteria and is adequate for this intended use.