August 3, 2018

Philips Medical Systems (Cleveland) Inc.
% Michael Chilbert, Ph.D., P.E.
Regulatory Affairs Engineer
595 Miner Road
CLEVELAND OH 44143

Re: K181797
Trade/Device Name: Philips CT Big Bore Sliding Gantry Configuration
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: June 22, 2018
Received: July 5, 2018

Dear Dr. Chilbert:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K181797

Device Name
Philips CT Big Bore Sliding Gantry Configuration

Indications for Use *(Describe)*
The Philips CT Big Bore 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. These systems are indicated for head and whole body X-ray Computed Tomography applications in oncology, vascular and cardiology, for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PHILIPS

510(k) Summary of Safety and Effectiveness

[As required by 21 CFR 807.92(c)]

Applicant's Name: Philips Medical Systems (Cleveland), Inc.

Address: 595 Miner Road
Cleveland, OH
44143 USA

Contact Person: Michael Chilbert, Ph.D., P.E.

Title: Regulatory Affairs Engineer

Address: 595 Miner Road
Cleveland, OH
44143 USA

Telephone number: +1 440 869-4576

E-mail: michael.chilbert@philips.com

510(k) Summary Date of Preparation: 15-June-2018

Device Trade Name: Philips CT Big Bore Sliding Gantry Configuration

Common or Usual Name: Computed Tomography X-ray system

Classification

Name: Computed Tomography X-ray system
Regulation: 21 CFR 892.1750
Class: II
Product Code: JAK
Panel: Radiology

Primary Predicate device K171850 - Phillips CT Big Bore

Classification

Name: Computed Tomography X-ray system
Regulation: 21 CFR 892.1750
Class: II
Product Code: JAK
Panel: Radiology

PHILIPS

Indications for Use

The Philips CT Big Bore Sliding Gantry Configuration 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. These systems are indicated for head and whole body X-ray Computed Tomography applications in oncology, vascular and cardiology, for 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.

Intended Use:

The Philips CT Big Bore Sliding Gantry Configuration is a Computed Tomography X-Ray System intended to produce images of the head and body to be used for diagnostic imaging in radiology and in oncology as part of treatment preparation and radiation therapy planning. These systems are indicated for head and whole body X-ray Computed Tomography applications in patients of all ages and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*.

Device Description:

The Philips CT Big Bore is available in three system configurations, the Oncology configuration the Radiology (Base) configuration, and the new Sliding Gantry configuration.

The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the Philips CT Big Bore 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 detector array, fixed to the Rotor frame
2. Patient Support (Couch) – supports the patient in a stationary position while the gantry moves in and out on a carriage.
3. Console - A two part subsystem containing a Host computer and display that is the primary user interface and the Common Image Reconstruction System (CIRS) – a dedicated, powerful image reconstruction computer

In addition to the above components and the software operating them, each system includes workstation 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.

The Sliding Gantry Configuration provides the following features.

- The patient table is stationary during the scan.
- Patient is located on the stationary table.
- To perform imaging, CT gantry rides on a carriage and moves over the patient.

Substantial Equivalence:

Primary Predicate Device: Phillips CT Big Bore
Manufacturer: Philips Medical Systems (Cleveland), Inc.
Predicate Device k#: K171850

The design, intended use and technology provided with the proposed Philips CT Big Bore Sliding Gantry Configuration is identical to the predicate device, Phillips CT Big Bore, and therefore is considered substantially equivalent.

Table 5-2: Substantial Equivalence Comparison
Comparison of the primary predicate device, Phillips CT Big Bore (K171850) versus the proposed Philips CT Big Bore Sliding Gantry Configuration

Feature	Philips CT Big Bore	Proposed Philips CT Big Bore Sliding Gantry Configuration	Comments
Gantry (Stator, Rotor, X-Ray Tube and Generator, Data Measurement System)	No change	No change	Identical
Software	No change	No change	Identical
Patient Support	Couch slides horizontally, Gantry is stationary	Couch is stationary in the horizontal axis, Gantry slides horizontally	See table 10.1 for details. This operational change does not introduce new hazards and has no effect on the safety or effectiveness of the device.
Console	No change	No change	Identical
Environmental Requirements	No change	No change	Identical

PHILIPS

Table 5-2: Substantial Equivalence Comparison Comparison of the primary predicate device, Phillips CT Big Bore (K171850) versus the proposed Philips CT Big Bore Sliding Gantry Configuration			
Feature	**Philips CT Big Bore**	**Proposed Philips CT Big Bore Sliding Gantry Configuration**	**Comments**
Horizontal Movements, minimum increments	No change	No change	identical
Horizontal position precision planning	No change	No change	identical
Horizontal position repeatability	No change	No change	identical
Horizontal speed	Maximum Speed = 185 mm/sec Minimum Speed = 0.5 mm/sec	Maximum Speed = 150 mm/sec Minimum Speed = 1 mm/sec	Clinical scans on Big Bore scanner use speeds in the range of 1mm/sec to 60mm/sec, thus there is no impact to these differences.
Horizontal (Linear) movement when emergency stop is actuated	No change	No change	Identical
Horizontal obstruction detection	Couch stops horizontal motion when obstructed.	Gantry stops horizontal motion when obstructed.	The operational change does not introduce new hazards.
Collision envelope	25 mm gap requirement is met. Operator is monitoring motion of couch in relation to the gantry.	25 mm gap requirement is met. Operator is monitoring the motion of the sliding gantry in relation to the stationary couch.	The operator is instructed to observe the patient position while performing the scan, as in the case of the predicate device. This operational change does not introduce new hazards.
Couch Vertical Movements	Controlled by CT (Gantry)	Patient support is provided by a third party couch, which operates independently.	This operational change does not introduce new hazards and has no effect on the safety or effectiveness of the device.

PHILIPS

Summary of Non-Clinical Testing:

This 510(k) premarket notification contains technical documentation, which demonstrates that the proposed Philips CT Big Bore Sliding Gantry Configuration is substantially equivalent to the primary predicate device, Phillips CT Big Bore in terms of safety and effectiveness. Testing was performed on the proposed Philips CT Big Bore Sliding Gantry Configuration according to the following international and FDA recognized consensus standards and FDA regulations and guidance documents:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Ed 3 2007-03, Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-3 Ed 2.1:2013-04 Medical electrical equipment -- Part 1-3: General requirements for basic safety - Collateral standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6: Ed 3.1 2013-10 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-44:Ed 3.1 2012 Medical electrical equipment -- Part 2-44: Particular requirements for the safety of X-ray equipment
- ANSI AAMI IEC 62304:2006 First Edition Medical device software -- Software life cycle processes
- IEC 62366 Ed 1.0 2015-02 Medical devices -- Part 1: Application of usability engineering to medical devices
- ISO 14971 *Medical devices – Application of risk management to medical devices* (Ed. 2.0, 2007-03-01)
- 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).
- Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff
- Code of Federal Regulations Title 21, Subchapter J – Radiological Health

Bench testing included basic CT performance tests on phantoms, safety tests and software tests for functional and non-functional attributes of the proposed Philips CT Big Bore Sliding Gantry Configuration.

CT Performance Metric	Values and ranges measured on phantoms
MTF	Cut-off: High Mode 16±2lp/cm; Standard Mode: 13±2 lp/cm
CTDIvol	Head: 10.61mGy/100mAs±25%; Body: 5.92mGy/100mAs±25% at 120kV
CT number accuracy	Water: 0±4HU
Noise	0.27% ± 0.04% at 120 kV, 250 mAs, 12 mm slice thickness, UA filter
Slice Thickness	0.5mm - 1.5mm at nominal 0.75mm; 1.0mm - 2.0mm at nominal 1.5mm

The completed verification test protocols cover the main system level requirements of the System Requirements Specification and the subsystem requirement specifications as well as the identified hazard mitigations from the Safety Risk Management Report. The traceability between the requirements, the hazard mitigations and the test protocols are described in the Traceability Matrix. The Traceability Matrix also shows the overall test results per requirement and per hazard mitigation.

The results of the functional and non-functional regression tests as well as the user interface verification are provided in the Traceability Matrix. The detailed results are provided in the Full System Verification Test Report.

The completed validation test plan identified the tasks, deliverables, methodology, requirements and the resources for validation of the intended use and meets customer needs.

The validation testing includes clinical validation and serviceability validation. The clinical validation covered requirements related to clinical workflows and features. The serviceability validation is planned to cover requirements related to installation, servicing and troubleshooting of the systems, which will be performed at system installation.

The validation test plan was executed as planned and acceptance criteria met for each requirement. All deviations found were analyzed based on the defect management process and are being dispositioned per process.

Conclusion: All verification and validation tests were executed according to the Philips Big Bore Sliding Gantry Configuration System Design Verification and Validation Plans. All deviations found were analyzed based on the defect management process and are being dispositioned per process. No unacceptable deviation exist.

Summary of Clinical Performance Testing

The proposed Philips CT Big Bore Sliding Gantry Configuration did not require a clinical study since substantial equivalence to the legally marketed predicate device was proven with the verification/validation testing.

Conclusion:

The test results demonstrate that the proposed Philips CT Big Bore Sliding Gantry Configuration 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.

Based on the supporting data provided in this Special 510(k) submission, the proposed Philips CT Big Bore Sliding Gantry Configuration is considered substantially equivalent to the primary predicate device, Philips CT Big Bore in terms of safety and effectiveness. There are no significant differences that may raise new issues of safety or effectiveness. Bench tests and user validation have been performed to demonstrate that the proposed Philips CT Big Bore Sliding Gantry Configuration is as safe and effective as the predicate Philips CT Big Bore, without raising any new safety and/or effectiveness concerns.