Philips Medical Systems (Cleveland) Inc.
Michael Chilbert
Regulatory Affairs Engineer
595 Miner Road
Cleveland, Ohio 44143

November 9, 2017

Re: K171850
Trade/Device Name: Philips CT Big Bore
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: October 10, 2017
Received: October 12, 2017

Dear Mr. Michael 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171850

Device Name
Philips CT Big Bore

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.

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Philips CT Big Bore

510(k) Submission

Section 5

510(k) Summary

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510(k) Summary of Safety and Effectiveness
[As required by 21 CFR 807.92(c)]

Applicant's Name: Philips Medical Systems (Cleveland), Inc.
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510(k) Summary Date of Preparation: 19-June-2017

Device Trade Name: Philips CT Big Bore

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 K033357 – AcQSim Multislice CT Scanner

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

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Indications for Use

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.

Intended Use:

The Philips CT Big Bore 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 currently available in two system configurations, the Oncology configuration and the Radiology (Base) 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) – carries the patient in and out through the Gantry bore synchronized with the scan
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.

Substantial Equivalence:

Primary Predicate Device: AcQSim Multislice CT Scanner
Manufacturer: Philips Medical Systems (Cleveland), Inc.
Predicate Device k#: K033357

The design, intended use and technology provided with the proposed Philips CT Big Bore is identical to the predicate device, AcQSim Multislice CT Scanner, and therefore is considered substantially equivalent.

Table 5-2: Substantial Equivalence Comparison
Comparison of the primary predicate device, AcQSim Multislice CT Scanner (K033357) versus the proposed Philips CT Big Bore

	AcQSim Multislice CT Scanner	Proposed Philips CT Big Bore	Comments
Design/Fundamental Scientific Technology			
Application	Head/Body	Head/Body	Identical
Scan Regime	Continuous Rotation	Continuous Rotation	Identical
No. of Slices	Up to 40	16/32	Both the predicate and proposed CT systems currently use a 24 mm wide detector providing 16 slices/channels. The proposed Philips CT Big Bore can increase the number of images to 32 from the 16 channels of data using an optional software algorithm called WARP or DAS. This is available on Ingenuity CT, K160743
Scan Modes	Surview Axial Scan Helical Scan	Surview Axial Scan Helical Scan	Identical
Minimum Scan Time	0.42 sec for 360° rotation	0.42 sec for 360° rotation	Identical
Image (Spatial) Resolution	15 lp/cm max.	16 lp/cm (±2 lp/cm).	Identical
Image Noise, Body, STD Res., 16.25 mGy	10.7	10.7	Identical
Image Matrix	Up to 1024 x 1024	Up to 1024 x 1024	Identical
Display	1024 x 1280	1024 x 1280	Identical
Host Infrastructure	Windows XP	Windows 7	Essentially the same, Windows based computer running iPatient system software, does not affect safety and effectiveness

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Table 5-2: Substantial Equivalence Comparison Comparison of the primary predicate device, AcQSim Multislice CT Scanner (K033357) versus the proposed Philips CT Big Bore			
	AcQSim Multislice CT Scanner	**Proposed Philips CT Big Bore**	**Comments**
CIRS Infrastructure	PC/NT computer based on Intel processor & custom Multiprocessor Array	Windows Vista & custom Multiprocessor Array	Identical, Windows based computer
Communication	Compliance with DICOM	Compliance with DICOM	Identical
Dose Reporting and Management	No	Compliance with MITA XR25 and XR29	MITA XR25 and XR29 compliance is currently available on Philips CT Big Bore systems and the predicate systems with v3.6 software or higher, does not affect safety and effectiveness
Generator and Tube			
Power (kW Output)	60 kW	80 kW (Software limited to 60kW)	Generator is FDA class I, 510(k) exempt, no change in functionality, physically the same. This change does not affect safety and effectiveness.
mA Range	30-500mA	20-665mA (Software limited to 500mA)	The impact of increasing the tube power is an extended mA range, difference in range does not affect safety and effectiveness.
kV Settings	80, 120, 140	80, 100, 120, 140	Provides another setting that may be useful in standard scanning, does not affect safety and effectiveness
Focal Spot	Dynamic Focal Spot	Dynamic Focal Spot in X axis	Identical
Tube Type	MRC 800	MRC Ice Tube (880)	Identical tube technology, the two tubes share the same anode, cathode, bearing, anode drive, and electrical interfaces, but differ in housing, does not affect safety and effectiveness
Detectors			
Slice Thicknesses	0.5, 0.625, 1.25, 2.5mm and various combinations up to 4x10mm	Helical: 0.67mm – 5mm Axial: 0.625mm – 12.5mm	Identical, slice thickness, does not affect safety and effectiveness.

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Table 5-2: Substantial Equivalence Comparison Comparison of the primary predicate device, AcQSim Multislice CT Scanner (K033357) versus the proposed Philips CT Big Bore			
	AcQSim Multislice CT Scanner	**Proposed Philips CT Big Bore**	**Comments**
Type	2.4 or 4 cm NanoPanel detector	2.4 cm NanoPanel	The detector for the Philips CT Big Bore is a revision of the detector that was used in the predicate, both detectors have the same design specifications but the detector used in the Philips CT Big Bore shows slightly better performance. Marketing may use the "Elite" nomenclature in the detector name. This change does not affect safety and effectiveness.
Scan Field of View	Up to 600 mm	Up to 600 mm	Identical
Detector Type	Single layer ceramic scintillator plus photodiode array	Single layer ceramic scintillator plus photodiode array	Identical
Gantry			
Gantry Tilt	± 30^0	± 30^0	Identical
Gantry Rotation Speed	143 RPM	143 RPM	Identical
Bore Size	850 mm	850 mm	Identical
Clinical Features			
Low dose CT lung cancer screening	Yes	Yes	The proposed Philips CT Big Bore has the same configuration with the Brilliance Big Bore cited in K153444 and belongs to the family of a series of CT devices cleared in K153444.
Communication between injector and scanner	SAS (Spiral Auto Start)	SAS and SyncRight	SyncRight is used in conjunction with the SAS to improve clinical workflow of contrast enhanced scanning. The functionality of the injector will not be altered by SyncRight; only starting the injector and, if necessary stopping of the injector as well as entering injection parameters is available from the scanner console. This modification does not affect the safety or effectiveness of the device.
DoseRight / Dose Management (K012238)	Yes	Yes and iDose^4	DoseRight was cleared under K012238, iDose is an extension of the existing feature DoseRight, and both provide the same basic function (low dose scanning). This feature does not affect the safety or effectiveness of the device.

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Table 5-2: Substantial Equivalence Comparison Comparison of the primary predicate device, AcQSim Multislice CT Scanner (K033357) versus the proposed Philips CT Big Bore			
	AcQSim Multislice CT Scanner	**Proposed Philips CT Big Bore**	**Comments**
Dose Modulation (part of DoseRight, above)	D-DOM and Z-DOM	D-DOM (Angular DOM) and Z-DOM FDOM, 3D-DOM	Dose Modulation function modulates the tube current based on patient body symmetry change. FDOM incorporates the features of Z-DOM and D-DOM and does not introduce new hazards, but only supports a mode which combines angular and longitudinal modulation. This feature does not affect the safety or effectiveness of the device.
Cone Beam Reconstruction Algorithm - COBRA	Yes	Yes	Identical
Axial 2D Reconstruction	Yes	Yes	Identical
Lung Nodule Assessment (K023785)	Yes	Yes	Identical
ECG Signal Handling	Yes	Yes	Identical
Cardiac Reconstruction	Yes	Yes	Identical
Bolus Tracking (K02005)	Yes	Yes	Identical
Calcium Scoring	Yes	Yes	Identical
Heartbeat Calcium Scoring (HBCS)	Yes	Yes	Identical
Virtual Colonoscopy	Yes	Yes	Identical
Pediatric Applications Support	Yes	Yes	Identical
Remote Workstation Option	Yes – MxView – later renamed Extended Brilliance Workstation	Yes – IntelliSpace Portal (K162025)	Change of name, no effect on the safety or effectiveness of the device.
Volume Rendering	Yes	Yes	Identical
Liver Perfusion	Yes	Yes	Identical
Dental Planning	Yes	Yes	Identical
Functional CT	Yes	Yes	Identical
Stent Planning	Yes	Yes	Identical
Retrospective Tagging	Yes	Yes	Identical
Prospective Cardiac Gating	Yes	Yes	Identical

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Summary of Non-Clinical Testing:

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

- IEC 60601-1:2006 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, 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 2.0:2008 Medical electrical equipment -- Part 1-3: General requirements for basic safety - Collateral standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6:2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-44:2009 Medical electrical equipment - Part 2-44: Particular requirements for the safety of X-ray equipment
- IEC 62304:2006 First Edition Medical device software -- Software life cycle processes
- ISO 14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, 2007)
- 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).
- 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 system.

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 test protocols cover the main system level software and hardware 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.

Conclusion: All verification tests were executed according to the System Verification Plan. There were no deviations to the System Verification Plan. All executed tests passed the specified requirements.

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

Summary of Clinical Testing:

The validation testing covered clinical validation, serviceability validation, manufacturing validation and validation by analysis. The clinical validation covered requirements related to clinical workflows and features. The serviceability validation covered requirements related to upgrade, installation, servicing and troubleshooting of the systems. The manufacturing validation covered requirements related to operations and manufacturing and the validation by analysis covered all other requirements that affect the end user that were not covered by the above testing.

Conclusion: The validation test plan was executed as planned and acceptance criteria met for each requirement. All defects were managed and closed. All validation tests of this Premarketing Notification [510(k)] submission demonstrates the safety and effectiveness of the Philips CT Big Bore in its performance as a CT system. The results of this validation testing are available in the Final Validation Report.

Sample clinical images were provided with this submission, which were reviewed and evaluated by radiologists. All images were evaluated to have good image quality.

The proposed Philips CT Big Bore has the same configuration as the Brilliance Big Bore cited in K153444, therefore the Philips CT Big Bore is cleared for low dose CT lung cancer screening.

The proposed Philips CT Big Bore can be used as defined in its clinical workflow and intended use.

Conclusion:

Philips believes that the proposed Philips CT Big Bore is substantially equivalent to the predicate device, AcQSim Multislice CT Scanner. 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 is as safe and effective as the predicate device, AcQSim Multislice CT Scanner, without raising any new safety and/or effectiveness concerns.