DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2017

Philips Medical Systems (Cleveland), Inc.
% Ms. Christine Anderson
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K162838
Trade/Device Name: Philips iCT CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 7, 2017
Received: March 9, 2017

Dear Ms. Anderson:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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)*
K162838

Device Name
Philips iCT CT System

Indications for Use *(Describe)*
The Philips iCT CT System 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 iCT 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.

*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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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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Contact Person:	Christine Anderson
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510(k) Summary Date of Preparation:	07-Mar-2017
Device Trade Name:	Philips iCT CT System
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
Predicate Device:	K060937 – Philips Brilliance Volume

Indications for Use:

The Philips iCT CT System 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 iCT 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.

*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.

Device Description:

The Philips iCT is currently available in two system configurations, iCT and iCT SP. Identical to the predicate, the Philips iCT CT System produces cross-sectional images of the body head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the Philips iCT 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 has an aperture of 700mm and consists of the following internal units:
    a. Stator – a fixed mechanical frame that carries hardware and software.
    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. The generator has a power rating of 100kW with optional 120kW.
    d. Data Measurement System (DMS) – a detectors array, fixed to the rotor frame. The DMS provides 8cm of coverage (4cm for the iCT SP configuration) and up to 256 slices (128 slices for the iCT SP configuration).The gantry offers 0.3 second rotation time (with optional 0.27s rotation).

2. Patient Table (aka Couch or Support) – carries the patient in and out through the Gantry bore synchronized with the scan. There are three available patient supports:
    a. Standard Table – provides maximum scannable range of 1750mm, longitudinal speed of 0.5mm/s-185mm/s and a maximum load capacity of 450 lbs.(204kg)
    b. Bariatric Table - provides maximum scannable range of 1750mm, longitudinal speed of 0.5mm/s-185mm/s and a maximum load capacity of 650 lbs.(295kg)
    c. Extended Table - provides maximum scannable range of 2100mm, longitudinal speed of 0.5mm/s-185mm/s and a maximum load capacity of 450 lbs.(204kg)
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.
4. Monitors
5. Software features to view and analyze images.

Substantial Equivalence:
Philips is citing substantial equivalence of the Philips iCT CT System to the Philips Brilliance Volume. The regulatory citations for the Brilliance Volume are listed below:
Predicate Device: Brilliance Volume
Predicate 510(k): K060937
Regulation: 21 CFR 892.1750
Class: II
Product Code: JAK
Panel: Radiology
Manufacturer: Philips Medical Systems (Cleveland), Inc.

The design, intended use and technology provided with the proposed Philips iCT CT System is equivalent to the currently marketed predicate.

Characteristics – Components/specifications	**Predicate: Brilliance Volume (K060937)**	**Proposed: Philips iCT**	**Comments**
Indications for Use	The “Brilliance Volume” is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different	The iCT 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	Indications for Use updated for proposed iCT to add reference to patients of all ages and low dose CT lung cancer screening (K153444). The predicate CT was also indicated for

Characteristics – Components/specifications	Predicate: Brilliance Volume (K060937)	Proposed: Philips iCT	Comments
	angles and planes. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.	include signal analysis and display equipment, patient and equipment supports, components and accessories. The iCT 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. *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.	patient of all ages, but it was not specifically stated in the indications.
Design/Fundamental Scientific Technology			
Application	Head/Body	Head/Body	No change
Scan regime	Continuous Rotation	Continuous Rotation	No change
Scan Modes	Surview Spiral (helical) Axial	Surview Helical Axial	No change
Gantry			
Gantry Aperture (Bore) size	700 mm	700 mm	No change

Characteristics – Components/specifications	Predicate: Brilliance Volume (K060937)	Proposed: Philips iCT	Comments
Gantry tilt	±30°	0°	The iCT Gantry does not have the tilt feature. This change does not affect safety or effectiveness.
Focus-isocenter distance	570 mm	570 mm	No change
Focus-detector distance	1040mm	1040mm	No change
Rotation times	0.3, 0.33, 0.375, 0.4, 0.5, 0.75, 1.0, 1.5 seconds for full 360° scans; 0.2 for partial angle 240° scans.(Optional - 0.27 seconds for full 360° scans; 0.18 seconds for partial angle 240° scans)	0.3, 0.33, 0.375, 0.4, 0.5, 0.75, 1.0, 1.5 seconds for full 360° scans; 0.2 for partial angle 240° scans.(Optional - 0.27 seconds for full 360° scans; 0.18 seconds for partial angle 240° scans)	No change
Patient Support/Couch/Table			
Patient Supports	Standard Bariatric	Standard Bariatric Extended (aka Long)	The predicate device released with two table options. The long, or extended, table was added to the CT System. The extended table allows for run off studies and does not affect safety or effectiveness.
Patient table scan range	1600 mm	Standard: 1750 mm Bariatric: 1750 mm Long: 2100 mm	The scannable range increased for the standard and bariatric patient supports. It does not affect safety or effectiveness.
Table Z-position accuracy	+/- 0.25 mm	Standard: +/- 0.25 mm Bariatric: +/- 0.25 mm Long: +/- 0.25 mm	No change
Table longitudinal speed	0.5 – 143 mm/sec	Standard: 0.5 – 185 mm/sec Bariatric: 0.5 – 185 mm/sec Long: 0.5 – 185 mm/sec	Slight increase in longitudinal speed. It does not affect safety or effectiveness

Characteristics – Components/specifications	Predicate: Brilliance Volume (K060937)	Proposed: Philips iCT	Comments
Table maximum load capacity	Standard: 450 lbs. (204kg) Bariatric: 650 lbs. (405kg)	Standard: 450 lbs. (204kg) Bariatric: 650 lbs. (405kg) Long: 450 lbs. (204kg)	No change
Generator and X-Ray Tube			
Generator power rating	100kW (120kW optional)	100kW (120kW optional)	No change
kVp settings	80, 100, 120, 140	80, 100, 120, 140	No change
mA range (step size)	10-830 (1mA steps), optional 10-1,000)	10-830 (1mA steps), optional 10-1,000)	No change
Focal spot size	small 0.6 x 0.7; large 1.1 x 1.2	small 0.6 x 0.7; large 1.1 x 1.2	No change
Anode effective heat capacity	30 MHU	30 MHU	No change
X-Ray tube, max. applied power	Dynamic Focal Spot in X and Z (2), up to 120kW, (8)	Dynamic Focal Spot in X and Z (2), up to 120kW, (8)	No change
X-Ray power supply	High-Frequency up to 120 kW, 10-1000 mA, 80-140 kV	High-Frequency up to 120 kW, 10-1000 mA, 80-140 kV	No change
Detector (DMS or Data Management System)			
Detectors	NanoPanel: Ceramic scintillator+ Photodiode 86016 elements - up to 128 slices simultaneously	iCT – same, but now with 256 slices iCT SP – 43008 photodiode elements for 128 slices	The material is the same as the predicate.
Slices	Brilliance Volume: 128	iCT configuration: 256 iCT SP configuration: 128	Slice increase is possible with the capability of the x-ray tube function.
Coverage	Brilliance Volume: 8 cm	iCT configuration: 8 cm iCT SP configuration: 4 cm	The iCT SP configuration has a 4 cm detector. It does not affect safety or effectiveness as compared to the predicate.
Collimations available	128 x 0.625 mm 64 x 0.625 mm 32 x 1.25 mm 16 x 2.5 mm 2 x 0.5 mm	iCT configuration: 128 x 0.625 mm 112 x 0.625 mm 96 x 0.625 mm 64 x 0.625 mm 32 x 0.625 mm 20 x 0.625 mm 16 x 0.625 mm 8 x 0.625 mm 4 x 0.625 mm 2 x 0.625 mm	The collimations identified for the proposed iCT and iCT SP are clarifications of the available collimations and needed by the user.

Characteristics – Components/specifications	Predicate: Brilliance Volume (K060937)	Proposed: Philips iCT	Comments
		64 x 1.25 mm 32 x 1.25 mm iCT SP configuration: 64 x 0.625 mm 32 x 0.625 mm 20 x 0.625 mm 16 x 0.625 mm 8 x 0.625 mm 4 x 0.625 mm 2 x 0.625 mm 64 x 1.25 mm 32 x 1.25 mm	
Slice Thickness	Helical mode 0.67 – 7.5 mm Axial mode 0.5 – 12 mm Axial or helical? 0.5, 0.625, 1.25, 2.5mm and various combinations up to 4x10mm	Helical mode 0.67mm – 10 mm Axial mode 0.625 mm – 10 mm	The slice thicknesses provided are clarifications of the original specifications.
Scan field	500 mm maximum	50 -500 mm continuous 25 - 250mm ultra-high resolution (UHR)	These are the same. The ultra-high resolution was not identified in the predicate 510(k)
Console computer (Common Host) and Common Image Reconstruction System (CIRS)			
Computer and CIRS (Common Image Reconstruction System)	PC/XP computer based on Intel processors and custom Multiprocessor Array	Windows 7 based on Intel processors and customer Multiprocessor Array.	The change to a Windows 7 based operating system does not affect safety or effectiveness.
Image matrix	512^2, 768^2, 1024^2	512^2, 768^2, 1024^2	No change

Summary of Non-Clinical Testing:

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.

Testing was performed on the proposed Philips iCT CT System according to the following international and FDA recognized consensus standards and FDA guidance documents:

- IEC 60601-1:2005+A1:2012 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 44: Particular requirements for the safety of X-ray equipment
- IEC 62304:2006 First edition medical device software – Software life cycle processes
- IEC 62366:2014 ED1.1 Medical devices -- Part 1: Application of usability engineering to medical devices
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

Design validation of user needs and intended use was conducted via simulated use testing with production equivalent Philips iCT 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 Philips iCT CT System meets system design requirements and user needs and intended use.

Summary of Clinical Testing:

The proposed Philips iCT 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.

Conclusion:

It is the conclusion of Philips that the proposed Philips iCT CT System is substantially equivalent to the predicate, Brilliance Volume. There are no significant differences that raise new issues of safety or effectiveness. The proposed Philips iCT CT and the

predicate produce images of the head and body by computer reconstruction of x-ray transmission data. As provided in the table above, design and fundamental technology, and subsystems such as the patient supports, generator, x-ray tube and detector of the proposed iCT CT System are either identical to the predicate or have minor changes that do not affect safety and effectiveness. Verification and validation testing, risk management activities and conformance to international standards demonstrate the safety and effectiveness of the proposed Philips iCT CT System. The comparison of the proposed Philips iCT CT System in regards to design and technology as well as successful completion of verification, validation and risk management activities demonstrate that the proposed Philips iCT CT System is as safe and effective as the predicate device.