



Food and Drug Administration  
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Philips Medical Systems (Cleveland), Inc.  
% Ms. Susan Quick  
Regulatory Affairs Specialist  
595 Miner Road  
CLEVELAND OH 44143

August 8, 2016

Re: K160743  
Trade/Device Name: Philips Ingenuity CT  
Regulation Number: 21 CFR 892.1750  
Regulation Name: Computed tomography x-ray system  
Regulatory Class: II  
Product Code: JAK  
Dated: July 18, 2016  
Received: July 20, 2016

Dear Ms. Quick:

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



Philips Ingenuity CT

510(k) Submission

Section 4

Indications For Use Statement

## Indications for Use

510(k) Number (if known)

K160743

Device Name

Philips Ingenuity CT

Indications for Use (Describe)

The Ingenuity CT 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 Ingenuity CT 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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## Philips Ingenuity CT 510(k) Submission

### Section 5

### 510(k) Summary Rev. 3



**510(k) Summary of Safety and Effectiveness**

*[As required by 21 CFR 807.92(c)]*

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**510(k) Summary Date of Preparation:** 29-February-2016

**Device Trade Name:** Philips Ingenuity CT

**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** K033326 – Philips Plus CT Scanner

**Indications for Use:** The Philips Ingenuity CT consists of three system configurations, the Philips Ingenuity CT, the Philips Ingenuity Core and the Philips Ingenuity Core<sup>128</sup>. These systems are Computed Tomography X-Ray Systems intended to produce cross-sectional images of the 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 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 Ingenuity CT is available in three system configurations, Ingenuity CT, Ingenuity Core, and Ingenuity Core<sup>128</sup>.

The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the Philips Ingenuity 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 - 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 a 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.

### Device Modifications

This 510(k) addresses the following minor changes (documented internally via a letter to file) that were implemented in the primary predicate device, Philips Plus CT System, cleared by FDA via 510(k) number K033326, (Oct. 29, 2003). **Table 5-1** provides a listing of the minor changes that were implemented since clearance of the predicate device, Philips Plus CT System.

<b>Table 5-1</b>	
<b>Table of minor changes that were implemented to the primary predicate device, Philips Plus CT System</b>	
<b>Design feature</b>	<b>Description</b>
Dell 670 host to Dell 690 host New CIRS computers	End of life components, no change in functionality
Generator, kV Settings	80KW and four kV settings (adding 100kV): the functionality is the same as on the 60KW generator and the addition of the 100 kV provides another setting that may be useful in standard scanning.
Generator Tube	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.
Detector	40 to 64 slices - The move to 64 slices was the addition of physical detectors increasing the total number of slices to 64.
	64 to 128 slices - With a reconstruction process and reduction in ("windmill") artifacts, 128 slices can be achieved from the 64 detectors.
	The NanoPanels of the predicate and the Ingenuity Core are the same, the NanoPanel Elite is a revision of the NanoPanel with slight performance improvements but still has the same product specifications.
Gantry Covers and Controls	Gantry Covers & Controls, CT Control Box: new cover design for gantry control/display panels, simplified CT control box for cost reduction.
Load and Unload Foot Pedals	Load and Unload foot pedals allow the operator to move the patient couch to the load or unload position using a foot pedal thus improving patient handling efficiency by freeing the operator's hands to prepare, restrain, or release the patient. The functionality was available in the predicate device through the Gantry panel buttons.
DMS Cover	Redesigned DMS cover for improved airflow and ventilation
Interventional Couch Control	Philips' interventional couch control, Panning Handle & Joystick, improves operational efficiency during CT-guided interventional procedures through tableside control of longitudinal movements for patient positioning. The functionality was available in the predicate device through the Gantry panel buttons.
IQ Improvement - Head Centering Application	The Head Centering Application helps to improve the brain image quality by giving the user the option to change the bed vertical position (height) after planning on Surview without forcing the user to re-plan the scan.
FDOM (Dose Modulation)	Dose Modulation function has been cleared on the Brilliance iCT submission K131773. This 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.
Low Dose Ring Artifact Reduction	Low Dose Ring Artifact Reduction is not a software feature or a software algorithm. This occurs when scanning at a low dose and/or scanning large attenuation objects. This was improved by making a change to the data collection process in the Detector Module System (DMS) which was achieved with the NanoPanel Elite detector. There is no new technology being introduced.
Pulmonary Gating	Is similar to the pulmonary gating of the AcQSim Multislice CT, K033357. Retrospective gating (tagging) was added to enhance the ease of use without significantly changing the device's safety and effectiveness.
CCT (Axial Step & Shoot)	The Step&Shoot (APEX) option is identical to the Axial Cardiac feature cleared in "Brilliance Volume" CT system K060937.

<b>Table 5-1</b>	
<b>Table of minor changes that were implemented to the primary predicate device, Philips Plus CT System</b>	
<b>Design feature</b>	<b>Description</b>
SyncRight	SyncRight has been cleared on the Ingenuity Digital PET/CT submission K123599. SyncRight is used in conjunction with the SAS to improve clinical workflow of contrast enhanced scanning. The SyncRight feature is supported by the communication between the injector and the CT scanner, to improve clinical workflow of contrast enhanced scanning.
Dose Management	The iDose <sup>4</sup> feature has been cleared most recently on the Brilliance iCT submission K131773. iDose <sup>4</sup> is an iterative reconstruction technique that improves image quality through artifact prevention and increased spatial resolution at low dose. It is comparable to the present Adaptive Filtering techniques and edge enhancing features used on the Brilliance 64.
iPatient	iPatient has been most recently cleared on the IQon Spectral CT submission K133674. iPatient was originally called “results driven scanning”, this software platform allows the operator to plan the required reconstruction results prior to the scan, without the need to go through the 2D images and re-recons. It enables the system to provide scan acquisition coverage based on the planned results. It does not affect image reconstruction or clinical algorithms, but only improves and simplifies the clinical workflow.
Reconstruction During Ready	Reconstruction During Ready has been cleared on the IQon Spectral CT submission K133674. This feature enables image construction of previous scans when the system is in “ready-for-scan” mode. The feature does not affect image reconstruction algorithms, but only reconstruction timing.
IMR	The IMR reconstruction feature has been cleared under K123576 for any Philips CT system with the stated minimum operational parameters. This is a purchasable option. The IMR (K123576) reconstruction feature is intended as an alternative to standard reconstruction methods (filtered back projection) for the reconstruction of CT scanner data to produce diagnostic images. The IMR reconstruction feature is designed to reduce image noise, increase high-contrast spatial resolution, and improve low contrast detectability. IMR is designed to reduce dose required for diagnostic CT imaging. Image quality improvements and dose reduction depend on the clinical task, patient size, anatomical location, and clinical practice.
iBrain/head filters	Brain/head reconstruction filters have been cleared on the IQon Spectral CT submission K133674. They work to improve Low Contrast Detectability by improving the Contrast to Noise Ratio (CNR) in brain images. The filters increase the contrast of white matter vs. gray matter resulting in better white matter/gray matter separation in brain scans.
Orthopedic Metal Artifact Reduction (O-MAR)	O-MAR stands for orthopedic metal artifact reduction. This post processing capability reduces metal induced artifacts and is directed for large orthopedics metals that cause photon starvation of the rays that pass through the metal object. Comparable to the MX 16-slice feature, K091195.
Advanced Brain Perfusion	This application was cleared under Brain Perfusion Option K033677 for use on the Philips Brilliance Workspace of a CT system. This Philips Brilliance Workspace is currently being used on the Philips Ingenuity CT.
Advanced Vessel Analysis (AVA)	These features were cleared under Brilliance CT, Private Practice CV Configuration CT Scanner K042293. The Philips Ingenuity CT and the Brilliance CT, Private Practice have the same CT functionality and both are using the same predicate device, the Philips Plus CT K033326. This feature functions the same on the Philips Ingenuity CT as it does on the Brilliance CT, Private Practice.
Comprehensive Cardiac Analysis (CCA)	

**Substantial Equivalence:** Primary Predicate Device: Philips Plus CT System  
 Manufacturer: Philips Healthcare  
 Predicate Device k#: K033326

The design, intended use and technology provided with the proposed Philips Ingenuity CT is identical to the predicate device Philips Plus CT System.

<b>Substantial Equivalence Comparison Table 5-2</b>			
	<b>Primary Predicate Device Philips Plus CT Scanner (K033326)</b>	<b>Proposed Philips Ingenuity CT (Ingenuity CT, Ingenuity Core, Ingenuity Core<sup>128</sup>)</b>	<b>Comments</b>
<b>Design/Fundamental Scientific Technology</b>			
Application	Head/Body	Head/Body	Identical
Scan Regime	Continuous Rotation	Continuous Rotation	Identical
No. of Slices	40	Ingenuity CT Configurations: Ingenuity CT – 128 Ingenuity Core – 64 Ingenuity Core <sup>128</sup> - 128	The move to 64 slices was the addition of physical detectors increasing the total number of slices to 64. With a reconstruction process and reduction in (“windmill”) artifacts, 128 slices can be achieved from the 64 detectors. Neither of these changes affect safety and effectiveness.
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)	24 lp/cm/max.	24 lp/cm/max.	Identical
Image Noise	0.27% at 120 kV, 250 mAs, 10 mm slice thickness	0.27% at 120 kV, 250 mAs, 10 mm slice thickness	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	Identical, Windows based computer running iPatient system software, does not affect safety and effectiveness.
Focal Spot	Dynamic Focal Spot	Dynamic Focal Spot in X axis	Identical
Power (kW Output)	60 kW	80 kW	Generator is FDA class I, 510(k) exempt, no change in functionality, physically the same. This change does not affect safety and effectiveness.

<b>Substantial Equivalence Comparison Table 5-2</b>			
	<b>Primary Predicate Device Philips Plus CT Scanner (K033326)</b>	<b>Proposed Philips Ingenuity CT (Ingenuity CT, Ingenuity Core, Ingenuity Core<sup>128</sup>)</b>	<b>Comments</b>
<b>Design/Fundamental Scientific Technology</b>			
mA Range	30-500mA	20-665mA	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.
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.
Scan Field of View	Up to 500 mm	Up to 500 mm	Identical
Detector Type	Single layer ceramic scintillator plus a photodiode	Single layer ceramic scintillator plus a photodiode	Identical
Gantry Tilt	± 30°	± 30°	Identical
Gantry Rotation Speed	143 RPM	143 RPM	Identical
Bore Size	700 mm	700 mm	Identical

**Summary of Non-Clinical Testing:**

This 510(k) premarket notification contains technical documentation, which demonstrates that the proposed Philips Ingenuity CT is substantially equivalent to the predicate device, Philips Plus CT System in terms of safety and effectiveness. Testing was performed on the proposed Philips Ingenuity CT according to the following international and FDA recognized consensus standards and FDA 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).

The completed bench test protocols included the above IEC standard requirements in addition to other requirements found in the main system level software 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.

Some of the bench tests included patient support/gantry positioning repeatability and accuracy, laser alignment accuracy, CT image quality metrics testing including CT number accuracy and uniformity within each slice for body and head, MTF, noise reduction performance of iDose<sup>4</sup>, slice thickness, slice sensitivity profiles and radiation metrics. Sample phantom images were provided to show the performance of the system in presence of implants, also when using a uniform phantom and a phantom with embedded test objects.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of this submission.

**Conclusion:** All verification tests were executed and passed the specified requirements, which validate that the subject device, Philips Ingenuity CT is substantially equivalent to the predicate device, Philips Plus CT Scanner, with regards to system performance.

## **Summary of Clinical Testing:**

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 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 system. 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.

The validation test plan was executed as planned and acceptance criteria met for each requirement. All defects were managed and closed. All validation tests demonstrate the safety and effectiveness of the Philips Ingenuity CT in its performance as a CT system. The results of this validation testing are available in the Final Validation Report.

An image evaluation was performed to compare images of the brain, chest, abdomen and pelvis/peripheral orthopedic body areas that were reconstructed using either FBP or an iterative reconstruction technique (iDose<sup>4</sup>). Images were compared using a 5 point Likert scale by a qualified radiologist to determine if the images were of diagnostic quality. Results indicated that there was no difference in image quality observed between the images reconstructed with iDose<sup>4</sup> compared to FBP reconstruction, with images reconstructed using iDose<sup>4</sup> scoring higher in most cases. Therefore there was no impact on diagnostic performance and images using iDose<sup>4</sup> which is provided on the Phillips Ingenuity CT are of diagnostic quality and equivalent to FBP reconstructed images provided on the predicate system.

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

**Overall****Conclusion:**

Based on the conformance to standards, development under Philips Medical System's quality system, the successful verification testing, additional engineering testing, and the clinical evaluation, Philips Medical Systems believes that the Philips Ingenuity CT is substantially equivalent to the predicate device Philips Plus CT Scanner (K033326). The proposed Philips Ingenuity CT is as safe and effective as the currently marketed and predicate device, Philips Plus CT Scanner, without raising any new safety and/or effectiveness concerns.