



Food and Drug Administration
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Philips Medical Systems (Cleveland), Inc.
% Michael Chilbert, Ph.D., P.E.
Quality & Regulatory Engineer
595 Miner Road
CLEVELAND OH 44143

April 8, 2016

Re: K153444

Trade/Device Name: Philips Multislice CT System with Low Dose CT Lung
Cancer Screening

Regulation Number: 21 CFR 892.1750

Regulation Name: Computed tomography x-ray system

Regulatory Class: II

Product Code: JAK

Dated: March 9, 2016

Received: March 10, 2016

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. 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned to the left of the printed name.

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

Indications for Use

510(k) Number (if known)

K153444

Device Name

Philips Multislice CT System with Low Dose CT Lung Cancer Screening

Indications for Use (Describe)

The Philips Multislice CT 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. The 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)

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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: 24-November-2015

Device Trade Name: Philips Multislice CT System with Low Dose CT Lung Cancer Screening

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

PHILIPS

Indications for Use

The indications for use of the currently marketed Philips Multislice CT Systems is the same as the proposed Philips Multislice CT Systems with Low Dose CT Lung Cancer Screening, provided below, except for the addition of lung screening indication noted in ***bold italic*** print:

The Philips Multislice CT 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. ***The 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:

Philips Low Dose CT Lung Cancer Screening option can be used with Philips whole body multi-slice CT X-Ray Systems installed in a healthcare facility (clinic / hospital). These systems provide a continuously rotating X-ray tube and detector array with multi-slice capability. The acquired x-ray transmission data is reconstructed by computer into cross-sectional images of the body taken at different angles and planes. Reconstruction algorithms available are standard reconstruction (filtered back projection), iDose⁴ and IMR iterative reconstruction. These systems also include signal analysis and display equipment, patient and equipment supports, components and accessories.

There are no functional, performance, feature, or design changes required for the qualified CT systems onto which the LDCT LCS Option is applied. Because none of the CTs will require hardware or software modifications, the Philips Low Dose CT Lung Cancer Screening option and the currently marketed and predicate Philips Multislice CT System for qualified CT systems in the installed base consists of:

- A set of up to three reference LDCT LCS protocols: standard reconstruction, standard reconstruction with iDose⁴, and with IMR iterative reconstruction (where applicable), for each qualified CT System on a per CT platform basis;
- Detailed instructions on how to create the protocols on the corresponding CT System; and



- A dedicated Instructions for Use for LDCT LCS that covers all qualified systems.

This submission is a bundled 510(k) based on the primary predicate K033326, adding a new Indication for Use to Philips multislice CT systems.

Table 1: The Philips Multislice CT Systems covered by the LDCT LCS Indications For Use

iCT Family (K060937)	IQon (K133674)	Brilliance 64/ Ingenuity Family (K033326)	Brilliance 16 Family (K012009)	Big Bore Family (K033357)
Brilliance iCT SP	IQon Spectral CT	Brilliance CT 40-channel	Brilliance 16-slice configuration	Brilliance CT Big Bore
Brilliance iCT		Brilliance CT 64-channel	Brilliance 16 Power	Brilliance CT Big Bore Radiology
iCT TVI		Brilliance CT 64-channel w/ Essence technology	Ingenuity Flex	Brilliance CT Big Bore Oncology
iCT Elite		Ingenuity Core	GEMINI 16 Power PET/CT	GEMINI TF Big Bore PET/CT
		Ingenuity Core128	GEMINI TF 16-slice	
		Ingenuity CT	TruFlight Select PET/ CT	
		Ingenuity Elite	GEMINI TF Ready PET/CT	
		Ingenuity TF PET/CT (64 & 128)	GEMINI LXL PET/CT	
		Vereos (64 & 128)		
		GEMINI TF 64-slice		

Intended Use:

Philips Low Dose CT Lung Cancer Screening option used in Philips Multislice CT 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.

Substantial Equivalence: The following review is performed for the Philips Multislice CT System with Low Dose CT Lung Cancer Screening 510(k) submission using the FDA Guidance for Industry on General/Specific Intended Use. Evaluation is provided for the guidance sections given below in support of substantial equivalence. The given level of specificity information and responses to the decision-making criteria show that the new Indication for Use (IFU) of Low Dose CT Lung Cancer Screening falls within the general intended use of the predicate devices. The procedures used for diagnostic imaging or screening are the same; scanning parameters may differ. This is demonstrated with lung nodule application (K023785), available on all the predicate systems. This application may be utilized in both diagnostic and screening evaluations. For the purpose of LDCT LCS, a target population is defined in NLST and I-ELCAP and these studies provide a considerable body of knowledge.

The level of specificity is defined as: a qualitative ranking of the proposed indications for use of a medical device. Levels of specificity for diagnostic and therapeutic devices in order of increasing specificity from general to specific can be categorized as follows:

Levels of Specificity for diagnostic medical devices:

1. Identification or measurement of a physical parameter or biochemical parameter
2. Identification of a new or specific target population (e.g., a certain age range) or anatomical location
3. Identification of the clinical use of the measurement (e.g., diagnosis, screening)
4. Identification of or implication of an effect on the clinical outcome

The level of specificity fits well within item 3, as this submission is adding an Indication for Use for Low Dose CT Lung Cancer screening. Level 2 specificity is applicable since LDCT LCS also identifies a new target population, based on the NLST trial. (N Engl J Med 2011; 365:395-409)

Decision-Making Criteria

The criteria that follow are provided as guidance on the Agency's decision-making process for determining substantial equivalence or non-equivalence for general/specific uses. ... These criteria should be evaluated in connection with the Levels of Specificity described earlier in this document.

1. *Risk*- Does a specific use introduce new risks not normally associated with the general use of the device?

There are no functional, performance, feature, or design changes required for the Qualified CT system onto which this option is applied. The imaging tasks for using low dose CT for Lung Cancer Screening as opposed to the use of CT when nodules are suspected are identical. No new technology is needed. The risk profile of the CT scanners do not change, as the design and capabilities of these systems remain the same. Risk associated with screening the target population versus the benefit of screening is described in NLST and I-ELCAP. (N Engl J Med 2011; 365:395-409)

2. *Public Health Impact*- Does a specific use impact public health to a significantly greater degree than the general use of the device? ...

The risks associated with a LDCT LCS program/protocol identified by the USPSTF are: false-negative and false-positive results; incidental findings; over-diagnosis; and radiation exposure. Philips has analyzed the Risk Management Matrix (RMM) of the Qualified CT systems and determined these risks are fundamentally the same as those associated with the use of CT when there is a suspicion that a nodule may be present. Any residual risk is the same as with general imaging and is therefore acceptable.

3. *Knowledge base*- Is there a body of evidence available to the agency regarding a proposed specific use that reflects existing understanding by the medical community that the more specific use is a subset of the general use, rather than a new intended use? That evidence can be derived from such sources as the medical literature and practice guidelines.

There has been much analysis in the literature about the risk vs. benefits of LDCT LCS for high risk populations using an established inclusion criteria and a LCS program protocol. The benefits have been demonstrated to outweigh the risks provided the screening is performed according to established inclusion criteria (e.g. for high risk populations) and in accordance with an established LDCT LCS program protocol. The published literature, clinical trials, and governmental review as well as multiple medical professional society endorsements have now come to the conclusion that

LDCT LCS performed under the above identified criteria is both safe and effective and provides a public health benefit to the high risk groups identified in the inclusion criteria.

4. *Endpoints*- To what degree can the performance or clinical endpoints (e.g., ability to ablate tissue; prevention of STDs) used to evaluate the general use be applied to the specific use?

The specific use (lung cancer screening for LDCT) does not impact public health to a significantly greater degree than the general use of LDCTs. The current use of CT provides significant public health benefit. Use for LDCT LCS only serves to increase the public health benefits. Large clinical trials such as NLST and I-ELCAP (N Engl J Med 2011; 365:395-409) demonstrate that there is a significant public health benefit for using LDCT LCS for the identified high risk populations using an established LCS program protocol.

Constraining the LDCT LCS indication for use to the populations outlined by the NLST and I-ELCAP clinical trials ensures a positive public health impact because screening is limited to the high risk groups medically and scientifically identified, with no impact on the general population.

Philips believes that there is more than sufficient scientific and medical evidence in the published literature and coverage decisions of the safety and effectiveness of LDCT LCS when performed with a pre-defined high risk group, according to a pre-defined screening program that includes dose targets.

5. *Tool or treatment?*- To what degree is the device used by the physician intended to perform a task as opposed to “being” the treatment ...?

The performance of the CT scanners is not changed; the modes of operation to accomplish low dose CT lung cancer screening are available on all Philips CT systems included in the submission.

6. *Adjunctive therapy*- To what degree does another product not routinely needed for the general use need to be used in conjunction with the device to achieve the specific use safely and effectively?

There are no adjunctive products required for lung cancer screening of the target population.

7. *Design changes*- To what extent does a modification to a medical device to facilitate the specific use render it less applicable to the other aspects of the general use?

There are no design changes to Philips CT systems to perform lung cancer screening of the target population. The qualified CT systems that include the lung cancer screening option continue to comply with the applicable US and international safety and performance standards such as Code of Federal Regulations Title 21, Subchapter J – Radiological Health, NEMA, DICOM, and IEC standards. The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

The design, intended use and technology provided with the proposed Philips Multislice CT System with Low Dose CT Lung Cancer Screening are identical to the currently marketed and predicate Philips Multislice CT System, and therefore are considered substantially equivalent

Summary of Non-Clinical Testing:

Non-clinical performance testing has been completed on Philips Multislice CT Systems and demonstrates substantial equivalence in the performance of the proposed Philips Multislice CT System with Low Dose CT Lung Cancer Screening. The currently marketed and predicate Philips Multislice CT Systems maintain compliance with the FDA performance and recognized consensus, as indicated in their original 510(k) submissions.

Demonstration of substantial equivalence for the currently marketed and predicate Philips Multislice CT System was done by a comparison of IQ metrics from Philips published specifications.

The results of non-clinical bench testing demonstrate that the image quality metrics including MTF, Image noise, CT number linearity, CT number accuracy, Slice Thickness, Contrast to Noise Ratio are substantially equivalent among different family of scanners (Brilliance 16, Brilliance Big Bore, Brilliance 64/Ingenuity, Brilliance iCT and IQon). The results of bench testing also demonstrate the image quality parameters for iDose⁴ and IMR reconstructions are equivalent to, or better than standard FBP reconstruction. The Noise Power Spectrum (NPS) curves were plotted for Standard FBP reconstruction, iDose⁴ and IMR.

Table 2: Image Quality Parameters and Inclusion Rationale for Substantial Equivalence

Image Quality Parameter	Reason for inclusion
Modulation Transfer Function (MTF)	<p>MTF is a measure of the high contrast spatial resolution performance of the system. Nodules in the lung are high contrast objects and therefore, MTF should be preserved at lower dose conditions.</p> <p>MTF is traditionally made at high contrast levels, of a wire or bar phantom. These high contrast measurements are not affected by noise. Certainly the noise levels of low dose lung cancer screening.</p>
Slice Thickness	<p>The ability to produce slice thicknesses (FWHM of the slice sensitivity profile) that are close to the nominal slice thickness is important in defining clear edges and boundaries of the nodule.</p> <p>Slice Thickness is also measured with a high density ramp or disk phantom. Like MTF these are not affected by noise levels used in LDCT LCS.</p>
CT number uniformity	<p>In a low dose scanning protocols such as with lung cancer screening, maintaining sufficient CT number uniformity throughout the lung and its various structures is important for more robust detectability of the nodules. Uniformity is needed to maintain CT number separation between structures. Uniformity is degraded by beam hardening. Beam hardening corrections are not degraded by noise. Added noise from low dose scanning makes beam hardening errors harder to see because they are buried in the noise.</p>
CT number linearity	<p>In a low dose scanning protocols such as with lung cancer screening, the CT number measured in a nodule may be affected and therefore measuring CT number linearity is important.</p> <p>Linearity is not affected by low dose scanning. The net effect is similar to Uniformity.</p>
Image noise (standard deviation)	<p>As dose is reduced, background noise in the image increases. If this noise becomes too large, nodule detectability and sizing measurement may be compromised.</p> <p>Noise goes up by the square root of the mAs. The contrast of the lung nodules is high relative to this increased noise, demonstrated by the CNR results (section 18) and NLST study.</p>
Noise Power Spectrum (NPS)	<p>Similar to the noise, changes in texture of the noise may have an influence on the nodule detection capabilities.</p> <p>The NPS scans were completed using the LDCT LCS scan protocol.</p>
Contrast to Noise (CNR)	<p>Sufficient Contrast-to-Noise is needed to detect solid and non-solid nodules in the lung. This parameter accounts for the contrast between an object and the background. This could also be a parameter that could influence nodule detectability.</p> <p>The CNR scans were completed using the LDCT LCS scan protocols for all scanners in the comparison.</p>

Since Philips does not have formal, published system level specifications for NPS and CNR, these metrics were evaluated specifically for demonstration of substantial equivalence.



Summary of Clinical Testing:

Philips believes that there is sufficient evidence in the published literature and coverage decisions of the safety and effectiveness of Low Dose CT Lung Cancer Screening when performed on a pre-defined high risk group, according to a pre-defined screening program that includes dose targets. Reference publications, clinical trials, medical professional society guides and recommendations, and governmental body review and recommendations form the clinical evidence that establishes the requisite safety and effectiveness.

Conclusion:

Philips believes that the proposed Philips Multislice CT System with Low Dose CT Lung Cancer Screening is similar to scanning applications that are incorporated in the currently marketed and predicate Philips Multislice CT System. There are no significant differences that may raise new issues of safety or effectiveness. Bench tests have been performed to demonstrate that the proposed Philips Multislice CT System with Low Dose CT Lung Cancer Screening is as safe and effective as the applications that are incorporated in the currently marketed and predicate Philips Multislice CT System, without raising any new safety and/or effectiveness concerns.