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 5, 2017

Philips Medical Systems (Cleveland), Inc.
% Mr. Steven Goldberg
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K163711
Trade/Device Name: IQon Spectral CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 15, 2017
Received: March 17, 2017

Dear Mr. Goldberg:

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)*
K163711

Device Name
IQon Spectral CT

Indications for Use *(Describe)*
The IQon Spectral CT 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 angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
The IQon Spectral CT system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and a lower- energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number.

This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures.
The system is also intended to be used 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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Section 5

510(k) Summary

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Section 5: 510(k) Summary – K163711

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	**March 14, 2017**	
Manufacturer:	Philips Medical Systems (Cleveland), Inc. 595 Miner Road Cleveland, OH 44143, USA Establishment Registration Number: 1525965	
Primary Contact Person:	Steven Goldberg Regulatory Affairs Specialist Phone: 972-(0)72-336-4218 E-mail: steven.goldberg@Philips.com	
Secondary Contact Person:	Michael S. Preto Senior Manager, Regulatory Affairs Phone: 440-483-2295 Fax: 440-483-4918 E-mail: Michael.preto@Philips.com	
Device:	Trade Name:	IQon Spectral CT
	Common name	Computed tomography x-ray system
	Classification Name:	Computed tomography x-ray system
	Classification Regulation:	21CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	II
	Primary Product Code:	JAK
	Secondary Product Code:	Not applicable
Primary Predicate Device:	Trade Name:	Philips IQon Spectral CT System
	Manufacturer:	Philips Medical Systems (Cleveland), Inc.
	510(k) Clearance:	K133674 (November 21, 2014)
	Classification Name:	Computed tomography x-ray system
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK

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Reference Device:	Trade Name:	Philips Multislice CT System with Low Dose CT Lung Cancer Screening
	Manufacturer:	Philips
	510(k) Clearance:	K153444 (April 8, 2016)

Device Description:

The IQon Spectral CT is a whole-body computed tomography (CT) X-Ray System featuring a continuously rotating x-ray tube and detectors gantry and 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. This device also includes signal analysis and display equipment; patient and equipment supports; components; and accessories. The IQon Spectral CT includes the detector array previously described in K133674 “Philips IQon Spectral CT”.

The IQon Spectral CT consists of three main components – a scanner system that includes a rotating gantry, a movable patient couch, and an operator console for control and image reconstruction; a Spectral Reconstruction System; and a Spectral CT Viewer. On the gantry, the main active components are the x-ray high voltage (HV) power supply, the x-ray tube, and the detection system.

In addition to the above components and the software operating them, the system includes workstation hardware and software for data acquisition; and image 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 minor modifications that were implemented in the currently marketed and predicate device, Philips IQon Spectral CT, cleared by FDA via 510(k) number K133674, Nov. 21, 2014. These minor changes include labeling clarifications, materials, components, defect fixes/improvements, and minor improvements to some spectral algorithms, e.g., Constant Noise Suppression, Pre Decomposition DeNoise, parameters tuning, and Iterative Bone Correction that were implemented since clearance of the currently marketed and predicate device, Philips IQon Spectral CT and do not change the indications for use of the device.

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This 510k also adds Low Dose CT Lung Cancer Screening in the Indications for Use, cleared by FDA for the reference device, Philips Multislice CT System with Low Dose CT Lung Cancer Screening via K153444, April 8, 2016.

Indications for Use:

The IQon Spectral CT 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 angles and planes. This device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The IQon Spectral CT system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and a lower- energy detected x-ray spectrum. The two spectra may be used to analyze the differences in the energy dependence of the attenuation coefficient of different materials. This allows for the generation of images at energies selected from the available spectrum and to provide information about the chemical composition of the body materials and/or contrast agents. Additionally, materials analysis provides for the quantification and graphical display of attenuation, material density, and effective atomic number.

This information may be used by a trained healthcare professional as a diagnostic tool for the visualization and analysis of anatomical and pathological structures.

The system is also intended to be used 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.

Technological Characteristics

The main components (detection system, the reconstruction algorithm, and the x-ray system) that are used in the proposed IQon Spectral CT System have the same fundamental design characteristics and are based on the same technologies as the

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currently marketed and predicate device, Philips IQon Spectral CT.
The design, indications for use, and the fundamental scientific technology provided with the proposed IQon Spectral CT are identical to the currently marketed and predicate device, Philips IQon Spectral CT.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the IQon Spectral CT System and demonstrates compliance with the following international and FDA-recognized consensus standards:

- International and FDA-recognized consensus standards:
  - IEC 60601-1:2005+A1:2012 (FDA reorganization number :19-4)
  - IEC 60601-1-2:2007 (FDA reorganization number :19-1)
  - IEC 60601-1-3 Edition 2.0:2008 (FDA reorganization number :12-210)
  - IEC 60601-1-6:2010 (FDA reorganization number :5-85)
  - IEC 60601-2-44:2009 (FDA reorganization number :12-257)
  - ISO 14971 Application of risk management to medical devices (2007) (FDA/CDRH reorganization number :5-40)
- Device specific guidance documents: 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)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014).

Non-Clinical verification and or validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results. The addition of lung cancer screening to the IFU statement was supported with a comparative assessment of image quality and technological characteristics to the devices cleared for this use in K153444.

Non Clinical verification and or validation test results demonstrate that the IQon Spectral CT System:

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- Complies with the aforementioned international and FDA-recognized consensus standards, 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), and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014).
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the IQon Spectral CT System is substantially equivalent to the currently marketed and predicate device, Philips IQon Spectral CT (K133674, Nov. 21, 2014) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The IQon Spectral CT System did not require a clinical study because substantial equivalence to the currently marketed and predicate device, Philips IQon Spectral CT, was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing;
- Labeling; and
- Safety and effectiveness.

Substantial Equivalence Summary:

The proposed IQon Spectral CT System is substantially equivalent to the currently marketed and predicate device, Philips IQon Spectral CT (K133674), in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Also, the Low Dose CT Lung Cancer Screening provided with the IQon Spectral CT System is substantially equivalent to the reference device, Philips Multislice CT System with Low Dose CT Lung Cancer Screening (K153444, April 8, 2016). Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the aforementioned international and FDA-recognized consensus standards. The results of these tests demonstrate that the IQon Spectral CT System met the acceptance criteria and is adequate for its intended use.