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

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

November 21, 2014

Re: K133674
Trade/Device Name: Philips IQon Spectral CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 23, 2014
Received: October 24, 2014

Dear Ms. Connell:

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,

Robert A Ochs

for

Janine M. Morris
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)*
K133674

Device Name
Philips IQon Spectral CT

Indications for Use *(Describe)*
The Philips 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.

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
[As required by 21 CFR 807.92(c)]

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510(k) Summary Date of Preparation:	23-October-2014
Device Trade Name:	Philips IQon Spectral 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
Predicate devices	Philips Brilliance iCT (K131773)

Device Description:

The Philips 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 Philips IQon Spectral CT includes the detector array previously described in K131773 "Modified Brilliance iCT".

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.

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Intended Use:

The Philips 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.

Substantial Equivalence: The Philips IQon Spectral CT has an intended use and technology that are similar to the predicate device.

As described above, the Philips IQon Spectral CT includes the hardware configuration previously described in K131773 "Modified Brilliance iCT", updated system software, a Spectral Reconstruction System; and a Spectral CT Viewer application.

The IQon Spectral CT system is able to generate conventional (combined) CT images (equivalent to a CT image series from a non-spectral detector CT system) as described in K131773. The scanner software has been updated to a more recent version of software that provides for an easier user workflow (iPatient).

To address the addition of spectral CT imaging capability, a reference device has been identified. Because both devices are able to acquire two CT spectra, each is able to perform various types of spectral analysis, such as:

- Monoenergetic images
- Materials Basis/Density Pairs, such as
  - I / H_20
  - I / Ca
  - Ca / Uric Acid
- Effective Atomic Number
- Material Separation/Differentiation
- Attenuation Curves
- Density Measurements/Visualization
- Reduction of Beam Hardening
- Reduction of Calcium Blooming

The Summaries of Non-Clinical Testing and Clinical Testing, presented below, provide a brief outline of the testing data that has been presented to demonstrate substantial equivalence.

Summary of Non-Clinical Testing:

The following tests demonstrated that the IQon Spectral CT system continues to conform to IEC 61223-3-5:2004:

- CT Number, Uniformity, Noise and Tomographic Section Thickness Measurements
- CTDI Dose Measurements
- Air Dose Measurements
- Spatial Resolution Measurements
- Low Contrast Detectability Measurements
- Acceptance and Constancy Test

Performance testing demonstrates following spectral capabilities:

- Monoenergetic Images - keV and HU stability
- Monoenergetic Images – CT linearity at 70 keV
- Iodine Quantification and Water-No-Iodine
- Iodine Map Imaging
- Calcium-No-Iodine images, and Iodine-No-Calcium images
- Calcium-No-Uric-Acid images, and Uric-Acid-No-Calcium images
- Virtual Non-Contrast (VNC) images
- Effective Atomic Number
- Beam Harding Artifact Reduction

Summary of Clinical Testing:

Clinical images were collected and analyzed, to ensure that images constructed by the IQon Spectral CT system meet user needs. This evaluation demonstrated that spectral images were useful for the visualization and analysis of anatomical and pathological structures.

Conclusion:

Philips Medical Systems (Cleveland), Inc. believes that, based on the information provided in this submission, the Philips IQon Spectral CT is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.