January 24, 2020

Philips Medical Systems, Nederland B.V.
% Nimit Shah
Regulatory Affairs Specialist
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

Re: K193454
Trade/Device Name: IQon Spectral CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 11, 2019
Received: December 13, 2019

Dear Nimit Shah:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K193454

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 analyse 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 and to be used for diagnostic imaging in radiology, interventional radiology, and cardiology and in oncology as part of treatment preparation and radiation therapy planning.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## SECTION 5 510(K) SUMMARY

# 510(k) Summary

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

**Date Prepared:** December 11, 2019

**Manufacturer:**
Philips Medical Systems Nederland B.V.
Veenpluis 4-6,
5684 PC BEST
The Netherlands
Establishment Registration Number: 3015777306

**Primary Contact Person:**
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Regulatory Affairs Specialists
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**Secondary Contact Person:**
Douglas Kentz
Director of Regulatory Affairs
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**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 |

**Predicate Device:**

| | |
|---|---|
| Trade Name: | Philips IQon Spectral CT |
| Manufacturer: | Philips Medical Systems (Cleveland), Inc. |
| 510(k) Clearance: | K163711 |
| Classification Name: | Computed Tomography x-Ray System |
| Classification Regulation: | 21CFR §892.1750 |
| Classification Panel: | Radiology |
| Device Class: | Class II |
| Product Code: | JAK |

**Device Description:**

The proposed IQon Spectral CT System 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 proposed IQon Spectral CT System includes the detector array, which is identical to the currently marketed and predicate device – Philips IQon Spectral CT System (K163711).

The proposed IQon Spectral CT System consists of three main components, that are identical to the currently marketed and predicate device, Philips IQon Spectral CT System (K163711) – 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 proposed IQon Spectral CT System includes workstation hardware and software for data acquisition; image display, manipulation, storage, and filming, as well as post-processing for views other than the original axial images. Patient supports (positioning aids) are used to position the patient.

**Indications for Use / Intended 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 analyse 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 and to be used for diagnostic imaging in radiology, interventional radiology, and cardiology and in oncology as part of treatment preparation and radiation therapy planning.

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 currently marketed and predicate device, Philips IQon Spectral CT (K163711)

The design, and the fundamental scientific technology provided with the proposed IQon Spectral CT System is identical to the currently marketed and predicate device, Philips IQon Spectral CT (K163711).

This 510(k) submission addresses the change of indication for use statement and minor modifications that were implemented in the currently marketed and predicate device Philips IQon Spectral CT (K163711). These minor modifications changes include labelling clarification, hardware obsolescence issues and software defect fixes/improvements, that were implemented since clearance of the predicate device. The additional changes that were introduced are as follows. The following changes do not impact device safety and effectiveness.

- Updated Indication for Use Statement: This update is only for clarification purposes by adding well known specific indications for use that are covered under the general indication for use statement. The currently marketed predicate device Philips IQon Spectral CT (K163711) is being used for diagnostic imaging in radiology, interventional radiology and cardiology and in oncology as part of treatment preparation and radiation therapy planning. The fundamental scientific technology and design of the proposed IQon Spectral CT system is identical with the currently marketed and predicate device Philips IQon Spectral CT System (K163711).
- Additional Optional Bariatric Couch (Patient Support)
- Hardware Options: 2nd CIRS Rack (Dual CIRS Rack – For Faster reconstruction) and Host Extension Kit (provides the ability to migrate the host from its default location in the control room within the Host Rack to the technical room within the CIRS rack. Both of these hardware options do not affect device safety and effectiveness.
- Electron Density: This is spectral CT image generated from an IQon spectral acquisition. A dedicated algorithm uses spectral data to estimate the electron density (ED) of each voxel. This change does not impact device safety and effectiveness and also does not alter intended use of the device.
- Calcium Suppression Index: This is HU-based spectral CT image generated from an IQon Spectral acquisition. A dedicated algorithm uses spectral data to identify and suppress calcium that normally overlays the underlying tissue. This change does not impact device safety and effectiveness and also does not alter intended use of the device.

Based on the information provided above, the proposed IQon Spectral CT System is considered substantially equivalent to the currently marketed and predicate device Philips IQon Spectral CT System (K163711), in terms of fundamental scientific technology.

**Summary of Non-Clinical Performance Data:**

Non-clinical performance testing has been performed on the proposed IQon Spectral CT system and demonstrates compliance with the following International and FDA recognized consensus standards and FDA guidance document(s).

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) (FDA Recognition Number: 19-4)
- IEC 60601-1-2:2014: (FDA Reorganization Number :19-8)
- IEC 60601-1-3:2008+A1:2013 (FDA Recognition Number: 12-269)

- IEC 60601-1-6:2010 +A1: 2013 (FDA Recognition Number: 5-89)
- IEC 60601-2-44:2009/AMD2:2016 (FDA Recognition Number: 12-302)
- IEC 62304:2006 + A1: 2015 (FDA Recognition Number: 13-79)
- ISO 10993-1:2009/Cor.1:2010 (FDA Recognition Number: 2-220)
- ISO 14971 2nd Edition. (FDA Recognition Number: 5-40)

Device Specific Guidance Document:

- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (issued October 2, 2014).

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 requirements specifications (SSRS) and the system level verification is conducted against the system requirement specifications (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.

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. The detailed results are provided in the Full System Verification Test Report.

Non-Clinical design validation testing covered the intended use and commercial claims as well as usability testing with representative intended users. Validation testing included clinical workflow validation and service validation.

All these tests were used to support substantial equivalence of the proposed IQon Spectral CT System and demonstrate that the proposed IQon Spectral CT System

- complies with the aforementioned international and FDA-recognized consensus standards and/or FDA device specific guidance document, and;
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the Proposed IQon Spectral CT is substantially equivalent to the currently marketed and predicate device Philips IQon Spectral CT (K163711) in terms of safety and effectiveness.

**Summary of Clinical Performance Data:**

The proposed IQon Spectral CT system did not require any external clinical study. The 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. The substantial equivalence to the currently marketed and predicate device Philips IQon Spectral CT (K163711) was demonstrated with the following attributes:

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

Sample clinical images were provided with this submission, which were reviewed and evaluated by certified radiologists. All images were evaluated to have good image quality.

**Substantial Equivalence Conclusion:**

The proposed IQon Spectral CT System is substantially equivalent to the currently marketed predicate device IQon Spectral CT (K163711) in terms of design, features and fundamental scientific technology. The change in indications for use statement is only for moving from general indication for use to specific indication for use for IQon Spectral CT. The updated Indication for Use Statement does not introduce any new risk nor impact safety and effectiveness of the proposed IQon Spectral CT System.

Additionally, substantial equivalence was demonstrated by non-clinical (verification and validation) performance tests provided in this 510(k) premarket notification. These tests demonstrate that proposed IQon Spectral CT system complies with the requirements specified by Philips Medical Systems Nederland B.V. and the international and FDA-recognized consensus standards and is as safe and effective as its currently marketed and predicate device Philips IQon Spectral CT (K163711) without raising any new safety and/or effectiveness concerns.