Philips Medical Systems Nederland B.V.
℅ Yaara Oltchik
Regulatory Affairs Project Manager
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

February 26, 2021

Re: K203020
Trade/Device Name: Spectral CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: January 22, 2021
Received: January 25, 2021

Dear Yaara Oltchik:

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,

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203020

Device Name
Spectral CT

Indications for Use *(Describe)*
The Spectral CT is a Computed Tomography X-Ray System intended to produce 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 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 in patients of all ages, 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.

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SECTION 5 510(K) SUMMARY

510(k) Summary

K203020

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

Date Prepared: January 18, 2021

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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Device*:*	Trade Name:	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 Nederland B.V.
	510(k) Clearance:	K193454
	Classification Name:	Computed Tomography x-Ray System
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK
Reference Device 1:	Trade Name:	Philips iCT CT System
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K162838
	Classification Name:	Computed Tomography x-Ray System
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK

Reference Device 2:

Trade Name:	Philips CT Big Bore
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K171850
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 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 Spectral CT System includes a detector array, which has spectral capability same as the cleared to market predicate device – Philips IQon Spectral CT System (K193454).

The proposed Spectral CT System consists of main components that are similar to the cleared to market predicate device, Philips IQon Spectral CT cleared under (K193454):

- Gantry -

On the rotating gantry, the main active components are:

  - x-ray high voltage (HV) power supply,
  - the x-ray tube,
  - detection system

- Patient couch
- Operator console for control
- Common Image Reconstruction Unit (CIRS)

In addition to the above components and the operating software, 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.
- Spectral Reconstruction System
- Spectral CT Viewer.

Indications for Use:

The 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 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 in patients of all ages, 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 Spectral CT System have the same fundamental design characteristics and are based on the same technologies as the cleared to market predicate device, Philips IQon Spectral CT (K193454)

The design/fundamental scientific technology of both the proposed Spectral CT System and the cleared to market predicate device Philips IQon Spectral CT (K193454) are the same. The design changes (e.g. larger bore size, 8 cm DMS, modified coach and additional SW features) do not change the fundamental scientific technology of the proposed Spectral CT System.

This 510(k) submission addresses modifications that were implemented in the cleared to market predicate device Philips IQon Spectral CT (K193454). These minor modifications include hardware and software enhancements and additional enhanced spectral results. The additional modifications that were implemented in the cleared to market predicate device Philips IQon Spectral CT (K193454) include:

Updated Indication for Use Statement:

- The indications for Use of the predicate device IQon Spectral CT (K193454) includes a clarification of the intended use population “in patients of all ages” to align with the recommendations of the “Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff (issued November 28, 2017)”. A detailed analysis of the proposed device and verification and/or validation testing in reference to the guidance has shown the proposed device Spectral CT meets the guidance recommendations therefore

demonstrating the safety and effectiveness of the device for the intended use population.

Hardware changes:

- Increase of Bore Size from 70cm to 80cm
- Increase in DMS Z coverage range from 4cm to 8cm
- Modified Couch, including increased maximal couch speed and acceleration, increased helical scan range and supported maximal patient weight.
- Interventional controls – workflow enhancements including HW and SW elements allowing to control the couch and system.

Added software features:

- Motion Compensated Reconstruction (MCR) (Cardiac) – a reconstruction technique for cardiac ECG-gated scans with the potential to provide compensation for cardiac motion.
- Virtual Tilt viewer (VTV) - a dedicated interactive image viewer available for interventional procedures.

Improved Spectral results:

- Spectral results for cardiac - The proposed Spectral CT introduces an improvement with spectral results intended for cardiac gated scans. This improvement is based on a modification of the previously cleared classification method to target calcified structures (rather than skeleton bones).
- Spectral results available also at 100kVp.

The aforementioned modifications implemented in the cleared to market predicate device Philips IQon Spectral CT (K193454) do not impact device safety and effectiveness.

Based on the information provided above, the proposed Spectral CT System is considered substantially equivalent to the cleared to market predicate device Philips IQon Spectral CT System (K193454), in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed 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: Medical electrical equipment - Part 1: General requirements for safety and essential performance
- IEC 60601-1-2:2014: Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3:2008+A1:2013: Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

- IEC 60601-1-6:2010 +A1: 2013: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
- IEC 60601-2-44:2009/AMD2:2016: Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- IEC 60825-1:2014 –Safety of laser products. Part 1: Equipment classification and requirements (pursuant to FDA Laser Notice 56 (May 2019) Laser Products)
- IEC 62304:2006 + A1: 2015: Medical device software - Software life-cycle processes
- IEC 62366-1:2015: Medical devices — Part 1: Application of usability engineering to medical devices ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

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).
- Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff (November 28, 2017)

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 demonstrates that the proposed Spectral CT system can be used as defined in its clinical workflow and intended use. The results of the summative usability validation indicate that the Spectral CT system has been found to be adequately safe and effective for the intended users, uses and use environments.

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

- complies with the aforementioned 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 Spectral CT is substantially equivalent to the cleared to market predicate device Philips IQon Spectral CT (K193454) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

There was no clinical testing conducted for the submission.

Substantial Equivalence Conclusion:

The proposed Spectral CT System is substantially equivalent to the cleared to market predicate device IQon Spectral CT (K193454) in terms of indications for use, design features and fundamental scientific technology.

The proposed device Spectral CT System is an evolution of predicate device Philips IQon Spectral CT (K193454) with the introduction of additional/enhanced design changes.

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 Spectral CT system complies with the design input requirements and the FDA-recognized consensus standards and that no new safety and/or effectiveness concerns were raised. Spectral CT is substantially equivalent and as safe and effective as it's cleared to market predicate device, Philips IQon Spectral CT (K193454).