May 13, 2022

Philips Medical Systems Nederland B.V.
% Maya Tolchinsky
Regulatory Affairs Specialist
Veenpluis 6
Best, 5684 PC
NETHERLANDS

Re: K212875
Trade/Device Name: Spectral CT on Rails
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: April 12, 2022
Received: April 15, 2022

Dear Maya Tolchinsky:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K212875

Device Name
Spectral CT on Rails

Indications for Use *(Describe)*

The Spectral CT on Rails 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 on Rails 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.

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

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

Date Prepared: September 2, 2021

Manufacturer: Philips Medical Systems Nederland B.V.
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The Netherlands
Establishment Registration Number: 3015777306

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Device*:*	Trade Name:	Spectral CT on Rails
	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:	Spectral CT
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K203020
	Classification Name:	Computed Tomography x-Ray System
	Classification Regulation:	21CFR §892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK
Secondary Predicate Device:	Trade Name:	Philips CT Big Bore Sliding Gantry Configuration
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K181797
	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 on Rails 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.
The proposed Spectral CT on Rails System consists of three main components: a rotating gantry that slides on a carriage in the horizontal direction, stationary patient support and an operator console for scan control and image reconstruction. On the gantry, the main active components are the X-ray HV power supply, the X-ray tube and the detection system.
The fundamental design and characteristics of the main components used in the proposed Spectral CT on Rails System, are identical to the cleared to market primary predicate device, Spectral CT System (K203020).

The proposed Spectral CT on Rails System consists of main components that are similar to the cleared for market primary predicate device, Spectral CT (K203020) Gantry. The Gantry consists of the following main internal units:
Stator – a fixed mechanical frame that carries HW and SW
Rotor – A rotating circular stiff frame that is mounted in and supported by the stator.
X-Ray Tube (XRT) and its power Generator, and the upper beam mechanism – fixed to the Rotor frame
Rails – the rails system includes a carriage which the gantry sits on so that it may be moved back and forth on the rails horizontally relative to a stationary patient support that the patient lays on. The moving gantry functionality has previously been cleared in, Philips CT Big Bore Sliding Gantry Configuration (K181797), secondary predicate device.
Data Measurement System (DMS) – a detectors array, fixed to the rotor in front of the XRT.
Console - A computer and display that interfaces between the system and the user.
Common Image Reconstruction Unit (CIRS) – a dedicated powerful image reconstruction system

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.
Spectral Reconstruction System
Spectral CT Viewer.

Indications for Use:

The Spectral CT on Rails 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 on Rails 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.

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 on Rails System have the same fundamental design characteristics and are based on the same technologies as the cleared to market primary predicate device, Spectral CT System (K203020).

The design/fundamental scientific technology of both the proposed Spectral CT on Rails System and the cleared to market primary predicate device, Spectral CT System (K203020) are the same. The design changes (e.g. patient support, horizontal movement, and horizontal motion range) do not change the fundamental scientific technology of the proposed Spectral CT on Rails System.
The following table lists the technological characteristics differences for the proposed Spectral CT on Rails

Table 05-1
Modifications made to the proposed device, Spectral CT on Rails as compared to the Primary predicate device, Spectral CT (K203020)

Design feature	Description
Couch	The proposed Spectral CT on Rails is not installed with a couch that can be controlled by the CT system.
Horizontal Movement	The Proposed Spectral CT on Rails moves the rotating gantry towards the patient who is positioned on a couch that is stationary in the horizontal axis; whereas the primary predicate system the rotating gantry was stationary and the couch was mobile in the horizontal axis.
Horizontal Motion Range	The Proposed Spectral CT on Rails has a larger range of horizontal motion that allows the user to move the Gantry away from couch to a parking position
Interventional Features	The proposed Spectral CT on Rails has enhanced interventional and interventional control features

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device:** Spectral CT (K203020)	**Proposed Device:** Spectral CT on Rails	**Conclusion**
Design and Fundamental Scientific Technology			
Application	Head, Body and Cardiac	Head, Body and Cardiac	**Identical**, therefore substantially equivalent.
Scan Regime	Continuous Rotation	Continuous Rotation	**Identical**, therefore substantially equivalent.
Scan Field of View	Up to 500 mm	Up to 500 mm	**Identical**, therefore substantially equivalent.
Scan modes	Surview Axial-after-Axial Dynamic Scan Helical Scan	Surview Axial-after-Axial Dynamic Scan Helical Scan	**Identical**, therefore substantially equivalent.
Spatial Resolution	16 lp/cm max (high mode) 13 lp/cm max (standard mode)	16 lp/cm max (high mode) 13 lp/cm max (standard mode)	**Identical**, therefore substantially equivalent.
Low Contrast Resolution (20 cm Catphan phantom)	4 mm @ 0.3% @ 25 mGy CTDIvol	4 mm @ 0.3% @ 25 mGy CTDIvol	**Identical**, therefore substantially equivalent.
Minimum Scan Time	0.18 sec for 240° rotation, 0.27 sec for 360° rotation	0.18 sec for 240° rotation, 0.27 sec for 360° rotation	**Identical**, therefore substantially equivalent.
Number of Slices	Up to 128 slices of 0.625 mm	Up to 128 slices of 0.625 mm	**Identical**, therefore substantially equivalent.
Scan Coverage	Scanner Center of Rotation (COR) is up to 80 mm	Scanner Center of Rotation (COR) is up to 80 mm	**Identical**, therefore substantially equivalent.
Noise in Standard Mode (as measured on 21.6 cm water-equivalent)	0.27% at 27 mGY	0.27% at 27 mGY	**Identical**, therefore substantially equivalent.
Image Matrix	Up to 1024 x 1024	Up to 1024 x 1024	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Display (Pixels)	1024 x 1280	1024 x 1280	**Identical**, therefore substantially equivalent.
Communication	Compliance with DICOM 3.0	Compliance with DICOM 3.0	**Identical**, therefore substantially equivalent.
Detectors			
Type	NanoPanel Prism	NanoPanel Prism	**Identical**, therefore substantially equivalent.
Material	Solid-state yttrium-based scintillator, GOS + Photodiode	Solid-state yttrium-based scintillator, GOS + Photodiode	**Identical**, therefore substantially equivalent.
DMS Detector	8 cm - Dual-Layer scintillator, up to 128 detector rows	8 cm - Dual-Layer scintillator, up to 128 detector rows	**Identical**, therefore substantially equivalent.
DMS structure	Spherical DMS structure	Spherical DMS structure	**Identical**, therefore substantially equivalent.
Detector structure			
Collimation	0.625 mm and various combinations, such as: 2x0.625, 16x0.625, 32x0.625, 64x0.625, 96x0.625, 112x0.625, 128x0.625 mm	0.625 mm and various combinations, such as: 2x0.625, 16x0.625, 32x0.625, 64x0.625, 96x0.625, 112x0.625, 128x0.625 mm.	**Identical**, therefore substantially equivalent.
Slice thickness	Various slice thickness options available in the range of 0.67 - 10 mm for helical mode and 0.625 – 20 for axial mode.	Various slice thickness options available in the range of 0.67 - 10 mm for helical mode and 0.625 – 20 for axial mode.	**Identical**, therefore substantially equivalent.
Scan field of view	Up to 500 mm	Up to 500 mm	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Gantry			
Gantry rotation speed	0.27 sec -1.5 sec (360° rotation) 0.18 sec, 0.2 sec (240° rotation)	0.27 sec -1.5 sec (360° rotation) 0.18 sec, 0.2 sec (240° rotation)	**Identical**, therefore substantially equivalent.
Bore size	800 mm	800 mm	**Identical**, therefore substantially equivalent.
Operator Controls located on Gantry	Touch Panel Controls	Touch Panel Controls	**Identical**, therefore substantially equivalent.
Eclipse Collimation	A-Plane	A-Plane	**Identical**, therefore substantially equivalent.
Generator and Tube			
Power	120kW	120kW	**Identical**, therefore substantially equivalent.
kV Setting	▪ 80 ▪ 100 ▪ 120 ▪ 140	▪ 80 ▪ 100 ▪ 120 ▪ 140	**Identical**, therefore substantially equivalent.
mA Range	10-1000	10-1000	**Identical**, therefore substantially equivalent.
Focal Spot- Smart Focal Spot	x- and z-deflection	x- and z-deflection	**Identical**, therefore substantially equivalent.
Conventional Reconstruction Speed	40 images per second	40 images per second	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
X-Ray Tube Type	iMRC	iMRC	**Identical**, therefore substantially equivalent.
Couch (Patient Support)			
Couch	Noah Couch	Couch is stationary in the horizontal axis, Gantry slides horizontally with rails system	**Substantially Equivalent.** The proposed Spectral CT on Rails does not use a couch that is controlled by the CT system to move the patient during scanning. Instead, the system controls gantry movement during scanning. This operational change does not introduce new hazards and has no effect on the safety or effectiveness of the device. The moving gantry functionality has previously been cleared in, Philips CT Big Bore Sliding Gantry Configuration (K181797), secondary predicate device.
Horizontal Movements, minimum increments	0.1mm	0.1mm	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Horizontal position precision planning	0.1mm	0.1mm	**Identical**, therefore substantially equivalent.
Horizontal speed	Maximum Speed = 600 mm/sec Minimum Speed = 1 mm/sec	Maximum Speed = 200 mm/sec Minimum Speed = 1 mm/sec	**Substantially Equivalent.** The gantry movement is limited by the gantry drive mechanism which is less than the couch drive mechanism of the primary predicate device Spectral CT (K203020) this difference does not raise new questions for safety and effectiveness. The moving gantry functionality has previously been cleared in, Philips CT Big Bore Sliding Gantry Configuration (K181797), secondary predicate device.
Collision envelope	25 mm gap requirement is met. Operator is monitoring motion of couch in relation to the gantry.	25 mm gap requirement is met. Operator is monitoring the motion of the sliding gantry in relation to the stationary couch.	**Identical**, therefore substantially equivalent.
General (Spectral)			
Technical Basis for Collection of two CT Spectra	Dual Layer DMS (Spectral Detector)	Dual Layer DMS (Spectral Detector)	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Spectral Base Images	▪ Low-energy ▪ High-energy ▪ Photoelectric ▪ Compton Scatter	▪ Low-energy ▪ High-energy ▪ Photoelectric Compton Scatter	**Identical**, therefore substantially equivalent.
Spectral results available [kVp]	▪ 100kVp ▪ 120kVp ▪ 140kVp	▪ 100kVp ▪ 120kVp ▪ 140kVp	**Identical**, therefore substantially equivalent.
Spectral Results Images	▪ Monoenergetic ▪ Materials Basis/Density Pairs, such as o I / H_20 o I / Ca o Ca / Uric Acid ▪ Effective Atomic Number ▪ Material Separation/ Differentiation ▪ Attenuation Curves ▪ Density Measurements/Visualization ▪ Reduction of Beam Hardening ▪ Reduction of Calcium Blooming ▪ Calcium Suppression Index ▪ Electron Density ▪ Spectral results for Cardiac	▪ Monoenergetic ▪ Materials Basis/Density Pairs, such as o I / H_20 o I / Ca o Ca / Uric Acid ▪ Effective Atomic Number ▪ Material Separation/ Differentiation ▪ Attenuation Curves ▪ Density Measurements/Visualization ▪ Reduction of Beam Hardening ▪ Reduction of Calcium Blooming ▪ Calcium Suppression Index ▪ Electron Density ▪ Spectral results for Cardiac	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
General (conventional and spectral)			
Cardiac reconstruction method	▪ Standard ECG Gated Reconstruction method ▪ Motion Compensated Reconstruction (MCR) (optional feature)	▪ Standard ECG Gated Reconstruction method ▪ Motion Compensated Reconstruction (MCR) (optional feature)	**Identical**, therefore substantially equivalent.
Virtual Tilt Viewer (VTV) (optional feature)	Yes	Yes	**Identical**, therefore substantially equivalent.
General			
HOST Drives	One 256 GB SSD for the OS and Console Software plus one 6 TB 7200 RPM HDD for results	One 256 GB SSD for the OS and Console Software plus one 6 TB 7200 RPM HDD for results	**Identical,** therefore substantially equivalent.
Host Infrastructure	Windows 10	Windows 10	**Identical,** therefore substantially equivalent.
CIRS Computers	▪ CIRS Rack that contains two HP Z8 servers. Option for two additional HP Z8 Servers in the same rack.	▪ CIRS Rack that contains two HP Z8 servers. Option for two additional HP Z8 Servers in the same rack.	**Identical**, therefore substantially equivalent.
CPUs	In CIRS each HP Z8: Dual Intel Gold 6230 with 20 cores at 2.1GHz each.	In each HP Z8: Dual Intel Gold 6230 with 20 cores at 2.1GHz each.	**Identical**, therefore substantially equivalent.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
CIRS Drives	In each HP Z8: 512GB NVMe SSD for OS and CIRS software, Two 2TB NVMe SSDs for raw data.	In each HP Z8: 512GB NVMe SSD for OS and CIRS software, Two 2TB NVMe SSDs for raw data.	**Identical**, therefore substantially equivalent.
Interventional features and controls	An on-screen indication crossed 80% & 100% of the accumulated CTDIVol threshold during the examination will actively appear each time the dose crosses the threshold	An on-screen indication crossed 80% & 100% of the accumulated CTDIVol threshold during the examination will passively appear each time the dose crosses the threshold	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement by allowing the on-screen indications to be passive and not interrupt to the interventional scans. The feature addition was made according to the Dose alerts standard NEMA XR-25 (2019). This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	There is no Check scan as the helical scan is not linked to the CCT scan.	The Check scan is a helical scan that is linked to a CCT scan. This linking is a user selection under All Parameters	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement by allowing a quick switching between CCT and helical scans. This contributes to the user comport to operate the system from the clinical exam room. This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.
	The operator enters the patient information to the CT system before each scan	When patient information is entered into a compatible Angio system, the same information can be used by the CT system. A prompt is sent to the CT console and when performing the CT scan all the patient information will be available and can be edited if required	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement by enabling the user to reuse patient information. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	The CT system status, errors and warnings are shown only in the console and not shown in the IVC box.	Rail system related Errors and warnings are added to the existing traffic light system in the console and those same errors and warnings are also displayed on the hardware Interventional Controls box (IVC).	Substantially Equivalent. The proposed enhanced feature introduces a usability improvement by adding the errors and warnings notifications to be presented on the IVC display. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.
	The user only be able to display the acquired anatomy using various display layouts with 1 or 3 images per shot and 0,1 reference images.	Multiple Display Layouts and Roadmaps allows the user to display the acquired anatomy using various display layouts with 1, 3 or 5 images per shot. User can choose from a defined set of display layouts for 1/3/5 images with 0,1 or 2 reference images from IVC or Console	Substantially Equivalent. The proposed enhanced feature introduces a usability improvement by enhancing the display layout options. This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	The user can only display the surview of the current examination as a reference image.	Real time CCT locations on Surview allows the user to display the surview of the current examination as a reference image. In addition, the user can also select to display indicators on that reference surview display indicators of: • Current Gantry position showing detector coverage (labeled “Current Position”) • Last scan Position with detector coverage (labeled “Last CCT”) • The selected view port's Image position (labeled “Active Viewport).	Substantially Equivalent. The proposed enhanced feature introduces a usability improvement by enhancing the display options on the surview. This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.
	The user needs to set orientation on each scan preformed.	Mirror options harmonization across viewers feature allows the user to apply selected orientation for all the completed results and successive results. In addition, the user can Rotate or Reset the option in CCT/Results Viewer from both Context Menu and Toolbox	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement for user comport by allowing the orientation settings to be fixed on multiple results. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	The user can use the CCT pedal only to start interventional Scans, and the CT Box Manual button is supporting only spiral scans	Start Helical Scan from Exam Room and CCT from Control Room feature allows the user to start Helical scan using CCT Pedal. In addition, the user can start CCT Single shot using CT Box Manual button	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement for user comport to perform additional scans from the exam room and the control room. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.
	The positioning of the plan box was not updated automatically following the selected bookmark position during plan.	Scan Position on Plan Viewer feature provides an automatically update of the scan plan box to match the selected bookmark position – Scan Position, Work Position or One of the Needle positions - as selected in the software Interventional Controls	Substantially Equivalent. The proposed enhanced feature introduces a usability improvement by providing automatic update to the plan box which helps the user perform the interventional scan. This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	To create oblique images, the user needs to load each corresponding image into the Slab Viewer.	Multi Planner Results (MPR) Improvements provides an additional capability in the Slab Viewer. The user can set an oblique view based on a previous scan, the same oblique result view are automatically generated for any subsequent scans for the same patient	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement by enable easy setup and copying of complex oblique-angle MPRs. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.
	Reconstructed images are sent image by image to the remote device	Push all images in one request feature provides a user preference to enable the user to send all the images together to a remote device	Substantially Equivalent. The proposed enhanced feature introduces data connectivity improvement by the adding the ability to push all images in one request. This enhancement feature does not alter the fundamental design, was successfully verified, and does not raise new questions on safety and/or effectiveness.

Table 05-2. Technological Characteristics Comparison			
Device Feature	**Primary Predicate Device: Spectral CT (K203020)**	**Proposed Device: Spectral CT on Rails**	**Conclusion**
Interventional features and controls	User will not be able to hide and unhide the SW Interventional Controls in the Console user interface	Scan ruler improvements feature allows the user to hide and unhide the SW Interventional Controls in the Console user interface	Substantially Equivalent. The proposed enhanced feature introduces a Usability improvement. This enhancement feature does not alter the fundamental design, was successfully verified and does not raise new questions on safety and/or effectiveness.
	User can turn on or turn off the laser markers only in the IVC, gantry panel.	Control Laser from Consoles feature allows the user to turn on or turn off the laser markers from the console user interface (in addition to the IVC and gantry panel).	Substantially Equivalent. The proposed enhanced feature introduces a workflow improvement by adding the option to control the laser from the gantry, IVC panel and console. This helps the user comport to operate the system from the clinical exam room. This enhancement feature does not alter the fundamental control mechanism, was successfully verified, and does not raise new questions on safety and/or effectiveness.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed Spectral CT on Rails 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.

The traceability between the requirements, the hazard mitigations and the test protocols are described in the traceability matrix.

The detailed verification results are provided in the Full System Verification Test Report. The results of the summative usability validation indicate that the proposed Spectral CT on Rails system has been found to be adequately safe and effective for the intended users, uses and use environments.

- Summary of Image Quality testing

Image quality comparison testing was performed between the proposed Spectral CT on Rails system and the cleared to market primary predicate Spectral CT (K203020).Two sets of Image Quality comparison testing were performed:

- Anthropomorphic phantom image review testing
- Image quality performance testing

Anthropomorphic phantom image review testing

- Purpose: The purpose of the test was to provide a summary and outcome of the anthropomorphic phantom image scans reviews for the proposed Spectral CT on Rails. In addition to compare image quality of the proposed Spectral CT on Rails to the cleared to market primary predicate device Spectral CT (K203020) image quality utilizing anthropomorphic phantom scans.
- Method and configurations: An anthropomorphic phantom was scanned on both scanners, the proposed Spectral CT on Rails and the cleared to market primary predicate device Spectral CT (K203020) using the same protocols. The scan types selected were determined to represent the anticipated usage of the proposed Spectral CT on Rails, with the CCT (continues CT) interventional scan types expected to be one of the primary uses for the scanner. Each scan was reviewed to determine if the two scanners produced comparable image quality.
- Summary results and Conclusion: The CCT anthropomorphic phantom scans on the proposed Spectral CT on Rails were found to have equivalent Image Quality as the scans from the cleared to market primary predicate device Spectral CT (K203020) for typical clinical applications. After the review of the clinical scenarios it was concluded that the image quality of the anthropomorphic phantom scans scanned on the proposed Spectral CT on Rails scanner was equivalent to the image quality of the cleared to market primary predicate device Spectral CT (K203020).

Image quality performance testing

- Purpose: The purpose of the image quality performance testing was to evaluate the image quality of the proposed Spectral CT on Rails system as compared to the cleared to market primary predicate device Spectral CT (K203020).
- Method and configurations: The image quality performance is measured on physics image quality test phantoms. Image quality performance: CT number, uniformity, noise, spatial resolution, low contrast resolution, slice thickness, and accuracy of spectral results, etc., have been compared between the scans performed on the proposed Spectral CT on Rails and cleared to market primary predicate device Spectral CT (K203020).
- Summary and results: No significant image quality performance difference has been observed on images acquired from the proposed Spectral CT on Rails (the gantry was moving during the scan and an angiography system couch was used to support the phantom) to those acquired from the 510(k) cleared to market primary predicate device Spectral CT (K203020) (the couch was moving during the scan and the CT couch was used to support phantom). The test successfully met the related system requirements of the proposed Spectral CT on Rails which are the same system requirements as those of cleared to market primary predicate device Spectral CT (K203020).
- Conclusion: The image quality of the proposed Spectral CT on Rails system is equivalent to the image quality of the 510(k) cleared to market primary predicate Spectral CT (K203020) system in terms of the quantitative image quality metrics.

The proposed Spectral CT on Rails was tested in accordance with Philips verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.
The test results in this 510(k) premarket notification demonstrate that the proposed Spectral CT on Rails

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the proposed Spectral CT on Rails is substantially equivalent to the cleared to market primary predicate device, Spectral CT System (K203020) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The subject of this premarket submission, the proposed Spectral CT on Rails did not require clinical studies to support equivalence

Substantial Equivalence Conclusion:

The proposed Spectral CT on Rails System is substantially equivalent to the cleared to market primary predicate device, Spectral CT System (K203020), in terms of indications for use, design features, fundamental scientific technology, and safety and/or effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance testing. The non-clinical performance tests (including image quality assessment testing) provided in this 510(k) premarket notification demonstrate that the proposed Spectral CT on Rails system is as safe and effective as its primary predicate device Spectral CT (K203020) without raising any new safety and/or effectiveness concerns.