May 16, 2025

Philips Medical Systems Technologies Ltd.
% Carmit Shmuel
Regulatory Affairs Manager and Site Lead
Advanced Technology Center, Building 34, MATAM
HAIFA, 3100202
ISRAEL

Re: K244008
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: February 3, 2025
Received: April 14, 2025

Dear Carmit Shmuel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244008

Device Name
Spectral CT

Indications for Use *(Describe)*

The Spectral CT system 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 support, 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 Extended field of view images and respiratory correlated scanning (4DCT) are for treatment preparation and radiation therapy planning/simulation usage only.

This device is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

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.

Based on the information provided above, the proposed Spectral CT system is considered substantially equivalent to the currently marketed primary predicate device, Spectral CT system (K203020), in terms of Indications for Use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K244008

510(k) Summary

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

Date Prepared:	February 03, 2025	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC BEST The Netherlands Establishment Registration Number: 3015777306	
Primary Contact Person:	Rachel Shalit Regulatory Affairs Specialist Phone: +972-54-9988057 E-Mail: rachel.shalit@philips.com	
Secondary Contact Person:	Carmit Shmuel Regulatory Affairs Manager and Site Lead Phone: +972-54-2109054 E-Mail: Carmit.Shmuel@philips.com	
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
	Product Code:	JAK
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:	21 CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK
Secondary Predicate Device:	Trade Name:	Spectral CT 7500 RT
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K240844
	Classification Name:	Computed Tomography X-ray System
	Classification Regulation:	21 CFR 892.1750
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	JAK

Device Description:

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 system also includes signals analysis and display equipment, patient and equipment support, components, 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 provides 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.

The Spectral CT system 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.

The fundamental design and characteristics of the main components used in the proposed Spectral CT system are identical to the currently marketed primary predicate device, Spectral CT system (K203020).

Indications for Use:

The Spectral CT system 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 support, 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 Extended field of view images and respiratory correlated scanning (4DCT) are for treatment preparation and radiation therapy planning/simulation usage only.

This device is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

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.

Based on the information provided above, the proposed Spectral CT system is considered substantially equivalent to the currently marketed primary predicate device, Spectral CT system (K203020), in terms of Indications for Use.

Technological Characteristics

The proposed Spectral CT system 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.
The design/fundamental scientific technology of the proposed Spectral CT system and the currently marketed primary predicate device, Spectral CT system (K203020) and recently cleared secondary predicate device Spectral CT 7500 RT system (K240844) are the same. The design changes (e.g. new software version and additional software features) do not change the fundamental scientific technology of the proposed Spectral CT system.

The following table 1 lists the technological characteristics differences for the proposed Spectral CT system:

Table 01 Modifications made to the proposed device, Spectral CT system as compared to the currently marketed primary predicate device, Spectral CT system (K203020)	
Design Feature	**Description**
Pulmonary Gating 4DCT	Pulmonary gated scanning is a new feature that allows CT scan data to be collected along with the patient's breathing signal in order to allow the CT data to be reconstructed into specific phases of breathing. This allows patient anatomy to be visualized during a breathing cycle usually to allow for breathing motion of both the target as well as organs at risk to be compensated for during radiation therapy treatment planning.
Extended Field of View (EFOV)	EFOV is a feature that allows for a maximum reconstructed FOV of up to 800mm for non-gated Helical scans only.

Table 2 provides a comparison which outlines a high-level overview of the differences and similarities between the proposed Spectral CT system and the primary currently marketed primary predicate device, Spectral CT system (K203020), including a brief discussion of how this comparison supports substantial equivalence.

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
Design and Fundamental Scientific Technology				
Application	Head, Body and Cardiac	Head, Body and Cardiac	Head, Body and Cardiac	**Identical**, therefore substantially equivalent.
Scan regime	Continuous Rotation	Continuous Rotation	Continuous Rotation	**Identical**, therefore substantially equivalent.
Scan Field of View	Up to 500 mm	Up to 800 mm	Up to 800 mm	**Substantially Equivalent.** **Substantially Equivalent.** Both the proposed device and the primary predicate device include a Scannable Field of View (SFOV) of 500mm used for reconstructed images. The improvement of the FOV in the proposed device for up to 800mm (Extended Field of View (EFOV)) is planned for Radiation Therapy Planning procedure and is identical from a technology perspective to the recently cleared secondary predicate device, Spectral CT 7500 RT (K240844). The SFOV was successfully verified and validated and does not raise new questions on safety and/or effectiveness.
No. of slices	Up to 128 slices of 0.625 mm	Up to 128 slices of 0.625 mm	Up to 128 slices of 0.625 mm	**Identical,** therefore, substantially equivalent
Scan modes	Surview Axial-after-Axial Dynamic Scan Helical Scan	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)	16 lp/cm max (high mode) 13 lp/cm max (standard	**Identical,** therefore, substantially equivalent

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
			mode)	
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	0.18 sec for 240° rotation, 0.27 sec for 360° rotation	**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	Scanner Center of Rotation (COR) is up to 80 mm	**Identical,** therefore, substantially equivalent
Low contrast resolution (32cm body CTDI phantom)	4 mm @ 0.3% @ 25 mGy CTDIvol	4 mm @ 0.3% @ 25 mGy CTDIvol	4 mm @ 0.3% @ 25 mGy CTDIvol	**Identical,** therefore, substantially equivalent
Noise in (as standard mode measured on 21.6 cm water-equivalent)	0.27% at 27 mGy	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	Up to 1024 x 1024	**Identical,** therefore, substantially equivalent
Display	1024 x 1280	1024 x 1280	1024 x 1280	**Identical,** therefore, substantially equivalent
Communication	Compliance with DICOM 3.0	Compliance with DICOM 3.0	Compliance with DICOM 3.0	**Identical,** therefore, substantially equivalent
Detectors				
Type	Nano Panel Prism	Nano Panel Prism	Nano Panel Prism	**Identical,** therefore, substantially equivalent
Material	Solid-state yttrium-based scintillator, GOS + Photodiode	Solid-state yttrium-based scintillator, GOS + Photodiode	Solid-state yttrium-based scintillator, GOS + Photodiode	**Identical,** therefore, substantially equivalent
DMS Detector Spectral CT 7500	8 cm - Dual-Layer scintillator, up to 128 detector rows	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	Spherical DMS structure	**Identical,** therefore, substantially equivalent
Collimation	0.625 mm and various combinations, such as:	0.625 mm and various combinations, such as:	0.625 mm and various combinations, such as:	**Identical,** therefore, substantially equivalent

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
	2x0.625, 16x0.625, 32x0.625, 64x0.625, 96x0.625, 112x0.625, 128x0.625 mm	2x0.625, 16x0.625, 32x0.625, 64x0.625, 96x0.625, 112x0.625, 128x0.625 mm	2x0.625, 16x0.625, 32x0.625, 64x0.625, 96x0.625, 112x0.625, 128x0.625 mm	
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)	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	800 mm	**Identical,** therefore, substantially equivalent
Operator Controls located on Gantry	Touch Panel Controls	Touch Panel Controls	Touch Panel Controls	**Identical,** therefore, substantially equivalent
Eclipse Collimation	A-Plane	A-Plane	A-Plane	**Identical,** therefore, substantially equivalent
Generator and Tube Performance				
Power	120kW	120kW	120kW	**Identical,** therefore, substantially equivalent
kV Setting	• 80 • 100 • 120 • 140	• 80 • 100 • 120 • 140	• 80 • 100 • 120 • 140	**Identical,** therefore, substantially equivalent
mA Range	10-1000	10-1000	10-1000	**Identical,** therefore, substantially equivalent
Couch				
Couch	Noah Couch	Noah Couch	Noah Couch	**Identical,** therefore, substantially equivalent
Couch Vertical Range	Minimum Height – 430 mm	Minimum Height – 430 mm	Minimum Height – 430 mm	**Identical,** therefore, substantially equivalent
Couch Horizontal Range	-2143 mm	-2143 mm	-2143 mm	**Identical,** therefore, substantially equivalent
Scannable Surview Range	1940mm	1940mm	1940mm	**Identical,** therefore, substantially equivalent

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
Scannable axial Range	2000mm	2000mm	2000mm	**Identical,** therefore, substantially equivalent
Scannable helical Range	1900mm	1900mm	1900mm	**Identical,** therefore, substantially equivalent
Couch Speed Range	1 mm/sec – 600 mm/sec	1 mm/sec – 600 mm/sec	1 mm/sec – 600 mm/sec	**Identical,** therefore, substantially equivalent
Acceleration	800 mm/Sec^2	800 mm/Sec^2	800 mm/Sec^2	**Identical,** therefore, substantially equivalent
Couch Max Load Capacity	High Performance: 675 lbs. (307 kg) Utilizing RTP flat tabletop optional accessory: 628 lbs. (285 kg)	High Performance: 675 lbs. (307 kg) Utilizing RTP flat tabletop optional accessory: 628 lbs. (285 kg)	High Performance: 675 lbs. (307 kg) Utilizing RTP flat tabletop optional accessory: 628 lbs. (285 kg)	**Identical,** therefore, substantially equivalent
Couch accessories	Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop	Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop	Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop	**Identical,** therefore, substantially equivalent
Clinical Applications: Dose Tools				
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)	Standard ECG Gated Reconstruction method Motion Compensated Reconstruction (MCR) (optional feature)	**Identical**, therefore substantially equivalent.
Virtual Tilt Viewer (VTV) (optional feature)	Yes	Yes	Yes	**Identical**, therefore substantially equivalent.
Pulmo & 4DCT (Four- Dimension Computed Tomography)	No	Yes	Yes	**Substantially Equivalent.** The proposed device, Spectral CT system introduces Pulmonary gated scanning which allows image acquisition of the esophagus and abdomen area while the patient is breathing. The Pulmonary gated scan

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
				feature is planned for Radiation Therapy Planning procedures and is similar from a technological perspective to the secondary recently marketed secondary predicate device, Spectral CT 7500 RT system (K240844). The Pulmonary gating was successfully verified and validated and does not raise new questions on safety and/or effectiveness
General				
Technical Basis for Collection of two CT Spectral	Dual Layer DMS (Spectral Detector)	Dual Layer DMS (Spectral Detector)		**Identical,** therefore, substantially equivalent
Spectral Base Images	Low energy High-energy Photoelectric Compton Scatter	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	100kVp 120kVp 140kVp	**Identical,** therefore, substantially equivalent
Spectral Results Images	Monoenergetic Materials Basis/Density Pairs, such as I / H20 I / Ca Ca / Uric Acid Effective Atomic Number Material Separation/ Differentiation Attenuation Curves Density Measurements/Visualizatio	Monoenergetic Materials Basis/Density Pairs, such as I / H20 I / Ca Ca / Uric Acid Effective Atomic Number Material Separation/ Differentiation Attenuation Curves Density Measurements/Visualization	Monoenergetic Materials Basis/Density Pairs, such as I / H20 I / Ca Ca / Uric Acid Effective Atomic Number Material Separation/ Differentiation Attenuation Curves Density Measurements/Visualizat	**Identical,** therefore, substantially equivalent

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
	n Reduction of Beam Hardening Reduction of Calcium Blooming Calcium Suppression Index Electron Density Spectral results for Cardiac	Reduction of Beam Hardening Reduction of Calcium Blooming Calcium Suppression Index Electron Density Spectral results for Cardiac	ion Reduction of Beam Hardening Reduction of Calcium Blooming Calcium Suppression Index Electron Density Spectral results for Cardiac	
Host Drives	256GB OS disk Plus one 7.68TB PCIE NVMe SSD	256GB OS disk plus one 7.68TB PCIE NVMe SSD	256GB OS disk plus one 7.68TB PCIE NVMe SSD	**Identical,** therefore, substantially equivalent
Host Infrastructure	Windows 10	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	CIRS Rack that contains two HP Z8 servers. Option for two additional HP Z8 Servers in the same rack	**Identical,** therefore, substantially equivalent
CIRS CPUs	In 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.	In each HP Z8: Dual Intel Gold 6230 with 20 cores at 2.1GHz each.	**Identical,** therefore, substantially equivalent
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.	In each HP Z8: 512GB NVMe SSD for OS and CIRS software, Two 2TB NVMe SSDs for raw data.	**Identical,** therefore, substantially equivalent

Table 2 – Technological Characteristics Comparison				
Design Feature	**Currently Marketed Primary Predicate Device:** Spectral CT system (K203020)	**Currently approved Secondary Predicate Device:** Spectral CT 7500 RT system (K240844)	**Proposed Device:** Spectral CT system	**Conclusion**
Interventional Controls	Yes	Yes	Yes	**Identical,** therefore, substantially equivalent

Based on the information provided above, the proposed Spectral CT system is considered substantially equivalent to the currently marketed primary predicate device, Spectral CT system (K203020), 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): (e.g., see below)

- IEC 60601-1:2005 A1:2012 A2:2020: Medical electrical equipment -- Part 1: General requirements for safety and essential performance (FDA recognition number: 19-49).
- IEC 60601-1-2:2014 A1:2020: Medical electrical equipment -- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA recognition number: 19-36).
- IEC 60601-1-3:2008 A2:2021: Medical electrical equipment -- Part 1: General requirements for safety -- 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment. (FDA recognition number: 12-336).
- IEC 60601-1-6:2010 A1:2013 A2:2020: Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability (FDA recognition number: 5-132).
- IEC 60601-2-28:2017: Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis (FDA recognition number: 12-309).
- IEC 60601-2-44:2009 A1:2012 A2:2016: Medical electrical equipment -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (FDA recognition number: 12-302).
- IEC 60825-1:2014 ISH1:2017 ISH2:2017: Safety measures, Light hazards, Lasers, Wavelengths, Eyes, Warning devices, Mathematical calculations, Medical equipment, Light emission, Marking, Hazards, Symbols, Instructions for use, Physiological effects (human body), Skin (body), Classification systems, Definitions, Occupational safety (FDA recognition number: 12-273).
- IEC 62304:2006 + A1:2015: Medical device software - Software life-cycle processes (FDA recognition number: 13-79).
- IEC 62366-1:2015 A1:2020: Medical devices - Application of usability engineering to medical devices (FDA recognition number: 5-129).
- ISO 14971:2019: Medical devices - Application of risk management to medical devices (FDA recognition number: 5-125).
- ISO 10993-1:2018: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (FDA recognition number: 2-258)

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).
- Guidance for Industry and FDA Staff – Content of Premarket Submissions for Device Software Functions (issued June 14, 2023).
- Pediatric Information for X-ray Imaging Device Premarket Notifications – Guidance for Industry and Food and Drug Administration Staff (November 28, 2017)
- Guidance for Industry and FDA Staff – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023)
- Guidance for Industry and FDA Staff – Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices (issued September 6, 2017)

Design verification planning and testing were conducted at the system level. The system is tested against the System Requirements Specifications (SRS). System verification activities demonstrate the system meets the established system design input requirements.

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

Design Validation tests the user needs and intended use that are documented in the top-level User Requirement Specification (PRS). The validation testing covered new features, clinical validation, and serviceability validation. All the validation tests as per validation plan were performed and acceptance criteria met for each of the requirements.
Non-clinical design validation testing demonstrates that the proposed Spectral CT system can be used as defined in its clinical workflow and intended use.

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

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

Therefore, the proposed Spectral CT system is substantially equivalent to the currently marketed primary predicate device, Spectral CT system (K203020), in terms of safety and effectiveness.

Summary of Clinical Performance Data:

Substantial equivalence to the currently marketed primary predicate device Spectral CT system (K203020) and the cleared secondary predicate device Spectral CT 7500 RT system (K240844) were demonstrated through the following attributes:

- Indication for use
- Technological characteristics
- Non-clinical performance testing
- Clinical Image Evaluation
- Safety and effectiveness

To support the evaluation of the new features, the submission includes:

- Phantom-based image quality (IQ) testing, assessing parameters such as noise, resolution, and artifacts
- A representative clinical image assessment
- Comparison of performance data against internal performance requirements

This data supports the safety, effectiveness, and substantial equivalence of the subject device.

Substantial Equivalence Conclusion:

The proposed Spectral CT system is substantially equivalent to the currently marketed primary predicate device, Spectral CT system (K203020) and currently cleared secondary predicate device Spectral CT 7500 RT system (K240844), in terms of indications for use, technological characteristics and principles of operation. The minor technological differences between the proposed Spectral CT system and currently marketed primary predicate device, Spectral CT system (K203020), raise no new issues of safety or effectiveness. Non-clinical performance data demonstrate that the proposed Spectral CT system performs as expected and in a manner that is substantially equivalent to its predicate device. Thus, the proposed Spectral CT system is substantially equivalent.