March 27, 2026

Philips Medical Systems Technologies, Ltd.
% Siwar Assi
Regulatory Affairs Team Lead
Advanced Technology Center, Matam, Bldg. 34
HAIFA, 3100202
ISRAEL

Re: K253649
Trade/Device Name: Spectral CT Verida Family
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: November 20, 2025
Received: February 26, 2026

Dear Siwar Assi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

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)*
K253649

Device Name
Spectral CT Verida Family

Indications for Use *(Describe)*
The Spectral CT Verida Family 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 Verida Family 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.
The system incorporates both conventional iterative reconstruction (IR) and artificial intelligence (AI)-based reconstruction functionality. Spectral Precise Image (SPI) is an AI-based deep learning reconstruction feature intended to optimize image quality by reducing noise and enhancing image appearance in Head, Whole Body, Cardiac, and Vascular X-ray Computed Tomography applications. Clinical performance evaluation of the SPI feature was conducted in adult patients (>22 years of age). The use of SPI in pediatric populations has not been clinically validated.
AI-based reconstruction outputs are intended to provide supplemental data for clinical interpretation and do not replace professional clinical judgment. Image quality and reconstruction performance may be subject to variability based on patient anatomy, body habitus, physiological motion, and technical acquisition conditions. It is the responsibility of the clinician to select the reconstruction method appropriate for the specific clinical task and patient population.
*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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# 510(K) SUMMARY (K253649)

This 510(k) summary of substantial equivalence information is prepared in accordance with 21 CFR 807.92(c).
Date Prepared: March 27, 2026

| SUBMITER INFORMATION | |
|---|---|
| Address | Philips Medical Systems Nederland B.V.<br>Veenpluis 6,<br>5684 PC Best,<br>Netherlands |
| Primary Contact | Siwar Assi<br>Regulatory Affairs Team Lead<br>Phone: +972-50-7494961<br>E-Mail: Siwar.Assi@philips.com |
| Secondary Contact | Carmit Shmuel<br>Regulatory Affairs Manager and Site Lead<br>Phone: +972-54-2109054<br>E-Mail: **Carmit.Shmuel@philips.com** |

| DEVICE IDENTIFICATION | |
|---|---|
| **Subject Device** | |
| Trade Name: | Spectral CT Verida Family |
| Common name: | System, X-ray, Tomography, Computed |
| Classification Name | Computed tomography x-ray system |
| Classification Regulation: | 21 CFR 892.1750 |
| Classification Panel: | Radiology |
| Device Class: | II |
| Product Code: | JAK |
| **Primary 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 |
| **Reference 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 |
| **Reference Device** | |
| Trade Name: | CT5300 |
| Manufacturer: | Philips Medical Systems Nederland B.V. |
| 510(k) Clearance: | K232491 |
| Classification Name: | Computed tomography x-ray system |
| Classification Regulation: | 21 CFR 892.1750 |
| Classification Panel: | Radiology |
| Device Class: | Class II |
| Product Code: | JAK |

## INTENDED USE / INDICATIONS FOR USE STATEMENT

### INTENDED USE

The Spectral CT Verida Family 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.

### INDICATIONS FOR USE

The Spectral CT Verida Family 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 Verida Family system acquires one CT dataset – composed of data from a higher-energy detected x-ray spectrum and 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.

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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.
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AI-based reconstruction outputs are intended to provide supplemental data for clinical interpretation and do not replace professional clinical judgment. Image quality and reconstruction performance may be subject to variability based on patient anatomy, body habitus, physiological motion, and technical acquisition conditions. It is the responsibility of the clinician to select the reconstruction method appropriate for the specific clinical task and patient population.

*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.

## DEVICE DESCRIPTION

The Spectral CT Verida Family 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 Verida Family 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 Verida Family 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 Verida Family system are identical to the cleared to market primary predicate device, Spectral CT 7500 RT system (K240844).

## TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE

The proposed Spectral CT Verida Family 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 both the proposed Spectral CT Verida Family system and the cleared to market primary 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 Verida Family system.

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

**Table 1: New/Modified features in the proposed device**

| **New/Modified Features** | **Description** |
|---|---|
| **Software Changes** | |
| Spectral Precise Image (SPI) | AI-based image denoising and image-quality enhancement functionality integrated within the image reconstruction pipeline. SPI is derived from the previously cleared Precise Image framework and does not alter the fundamental image-formation process or introduce new clinical decision-making functionality. |
| Spectral Result Generation Pipeline Optimization | Implemented this pipeline optimization to improve the Spectral Image Time-to-First-Image (TTFI). |
| Software Revision | Revision from Version 5.2 to Version 5.4 to accommodate for changes made under this version control. |
| **Hardware Changes** | |
| Noah RT-2 Couch | The proposed Spectral CT Verida Family system introduces Noah RT-2 Couch to replace the Noah HP Couch from the cleared to market primary predicate device, Spectral CT 7500 RT device (K240844). |
| Bayonet Head Holder | The Bayonet Head Holder provides additional scannable range when plugged into the couch head slot of the proposed Spectral CT Verida Family system. |
| Console and CIRS Computers | Change from HP G4 to HP G5 due to EOL and performance improvements |
| Oncology Tabletop | Change to support both Varian and Elekta indexing |

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**Table 2 Technological Characteristics Comparison**

| | **Proposed Device Spectral CT Verida Family** | **Primary Predicate Device Spectral CT 7500 RT (K240844)** | **Reference Device Spectral CT (K203020)** | **Reference Device CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **TECHNOLOGICAL CHARACTERISTICS** | | | | | |
| **Application** | Head, Body, and Cardiac | Head, Body, and Cardiac | Head, Body, and Cardiac | Head, Body, and Cardiac | **Same as primary predicate** |
| **Scan regime** | Continuous Rotation | Continuous Rotation | Continuous Rotation | Continuous Rotation | **Same as primary predicate** |
| **Computer and CIRS (Common Image Reconstruction System)** | PC computer based on Intel processors and custom Multiprocessor Array | PC computer based on Intel processors and custom Multiprocessor Array | PC computer based on Intel processors and custom Multiprocessor Array | PC computer based on Intel processors and custom Multiprocessor Array | **Same as primary predicate** |
| **Display** | 1280 x 1024 | 1280 x 1024 | 1280 x 1024 | 1920 x 1080 | **Same as primary predicate** |
| **Number 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 | Up to 128 slices of 0.625 mm | **Same as primary predicate** |
| **Scan modes** | Surview<br>Axial-after-axial<br>Dynamic Scan<br>Helical Scan | Surview<br>Axial-after-axial<br>Dynamic Scan<br>Helical Scan | Surview<br>Axial-after-axial<br>Dynamic Scan<br>Helical Scan | Surview<br>Axial-after-axial<br>Helical Scan | **Same as primary predicate** |
| **Minimum Scan time** | 0.18 sec for 240° rotation,<br>0.27 sec for 360° rotation | 0.18 sec for 240° rotation,<br>0.27 sec for 360° rotation | 0.18 sec for 240° rotation,<br>0.27 sec for 360° rotation | 0.35 sec for 360° rotation | **Same as primary predicate** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **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 | Focus-isocenter distance: 570 mm | **Same as primary predicate** |
| **Image Matrix** | Up to 1024 x 1024 | Up to 1024 x 1024 | Up to 1024 x 1024 | Up to 1024 x 1024 | **Same as primary predicate** |
| **Spatial Resolution** | 16 lp/cm max (high mode) | 16 lp/cm max (high mode) | 16 lp/cm max (high mode)<br>13 lp/cm max (standard mode) | 16 lp/cm max (high mode)<br>13 lp/cm max (standard mode) | **Same as primary predicate** |
| **Low Contrast Resolution** | 4.0 mm at 0.3% with 25 mGy (CTDIvol) | 4.0 mm at 0.3% with 25 mGy (CTDIvol) | 4.0 mm at 0.3% with 25 mGy (CTDIvol) | Low-contrast resolution (with iDose4): 2 mm @ 0.3%; ≤ 42mGy CTDIvol (body), 3 mm @ 0.3%; ≤ 22 mGy CTDIvol (body), 4 mm @ 0.3%; ≤ 15.5 mGy CTDIvol (body), 5 mm @ 0.3%; ≤ 14 mGy CTDIvol (body)<br>Low-contrast resolution (with | **Substantially equivalent;** |

| | **Proposed Device Spectral CT Verida Family** | **Primary Predicate Device Spectral CT 7500 RT (K240844)** | **Reference Device Spectral CT (K203020)** | **Reference Device CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | Precise Image): 5 mm @ 0.3%; ≤ 5.5 mGy CTDIvol (body) | |
| **Noise in Standard Mode (as measured on 21.6 cm water-equivalent)** | 0.27% at 27 mGy | 0.27% at 27 mGy | 0.27% at 27 mGy | ≤0.18% at 120kV, 230mAs, CTDIcenter(head) ≤ 33mGy, 10mm image thickness, iDose4 | **Same as primary predicate** |
| **DETECTORS** | | | | | |
| **DMS Detector** | 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 | Single layer ceramic scintillator plus a photodiode | **Same as primary predicate** |
| **Material** | Solid-state yttrium-based scintillator, GOS + Photodiode | Solid-state yttrium-based scintillator, GOS + Photodiode | Solid-state yttrium-based scintillator, GOS + Photodiode | Solid-state GOS with 43,008 elements | **Same as primary predicate** |
| **Type** | NanoPanel Prism Precise 3rd Gen | NanoPanel Prism | NanoPanel Prism | NanoPanel Elite | **Same as primary predicate The brand name of the detector is updated in Spectral CT** |

| | **Proposed Device Spectral CT Verida Family** | **Primary Predicate Device Spectral CT 7500 RT (K240844)** | **Reference Device Spectral CT (K203020)** | **Reference Device CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **Verida Family to NanoPanel Prism Precise 3rd Gen. No difference in characteristics between products, no impact to safety or effectiveness of the device.** |
| **DMS structure** | Spherical DMS structure | Spherical DMS structure | Spherical DMS structure | Spherical DMS structure | **Same as primary predicate** |
| **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. | 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 1.25 mm various combinations, such as: 2x0.625, 4x0.625, 12x0.625, 16x0.625, 32x0.625, 64x0.625, 12x1.25, 32x1.25 mm | **Same as primary predicate** |
| **Slice thickness** | Various slice thickness options available in the range of 0.67 - 10 mm for helical mode and | Various slice thickness options available in the range of 0.67 - 10 mm for helical mode and | Various slice thickness options available in the range of 0.67 - 10 mm for | Helical: 0.67mm – 5mm Axial: 0.625mm – | **Same as primary predicate** |

| | **Proposed Device Spectral CT Verida Family** | **Primary Predicate Device Spectral CT 7500 RT (K240844)** | **Reference Device Spectral CT (K203020)** | **Reference Device CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | 0.625 – 10 for axial mode | 0.625 – 10 for axial mode | helical mode and 0.625 – 10 for axial mode | 10.0mm | |
| **Scan field of view** | Up to 500 mm | Up to 500 mm | Up to 500 mm | Up to 500 mm | **Same as primary predicate** |
| **EFOV- Extended Field Of View** | Yes; Up to 800 mm | Yes; Up to 800 mm | No | No | **Same as primary predicate** |
| **GENERATOR AND TUBE** | | | | | |
| **Gantry Bore Aperture diameter** | 800 mm | 800 mm | 800 mm | 720mm | **Same as primary predicate** |
| **Gantry rotation speed** | 0.27 sec -1.5 sec (360° rotation)<br>0.18 sec, 0.2 sec (240° rotation) | 0.27 sec -1.5 sec (360° rotation)<br>0.18 sec, 0.2 sec (240° rotation) | 0.27 sec -1.5 sec (360° rotation)<br>0.18 sec, 0.2 sec (240° rotation) | 171 RPM | **Same as primary predicate** |
| **Operator Controls located on Gantry** | Touch Panel Controls | Touch Panel Controls | Touch Panel Controls | Touch Panel Controls | **Same as primary predicate** |
| **Eclipse** | A-Plane | A-Plane | A-Plane | N/A | **Same as** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **Collimation** | | | | | **primary predicate** |
| **Power** | Up to 120 kW | Up to 120 kW | Up to 120 kW | 55kW/72kW/80kW | **Same as primary predicate** |
| **kV Setting** | 80, 100, 120, 140 | 80, 100, 120, 140 | 80, 100, 120, 140 | 70, 80, 100, 120, 140 | **Same as primary predicate** |
| **mA Range** | 10-1000 | 10-1000 | 10-1000 | 5-667 | **Same as primary predicate** |
| **Focal Spot** | Dynamic Focal Spot in X and Z | Dynamic Focal Spot in X and Z | Dynamic Focal Spot in X and Z | Dynamic Focal Spot in X-axis | **Same as primary predicate** |
| **Conventional Reconstruction Speed** | 120 image per sec | 40 images per sec | 40 images per sec | Reconstruction speed (standard console)<br>Essentials: Up to 80 IPS<br>Essentials 64: Up to 60 IPS<br><br>Reconstruction speed (enhanced console)<br>Up to 100 IPS | **Substantially equivalent; Reconstruction performance improvements for conventional CT is a part of this change on the proposed** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **Spectral CT Verida Family. The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **X-Ray Tube Type** | iMRC | iMRC | iMRC | vMRC Performance | **Same as primary predicate** |
| **COUCH (PATIENT SUPPORT)** | | | | | |
| **Couch** | Noah RT-2 Couch | Noah HP Couch | Noah HP Couch | Standard Couch<br>Noah HP Couch | **Substantially equivalent;**<br>**The proposed Spectral CT Verida Family introduces Noah RT-2 Couch to replace Noah HP Couch in cleared** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **to market primary predicate device Spectral CT 7500 RT system (K240844).**<br>**The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **Horizontal position precision planning** | 0.1mm | 0.1 mm | 0.1mm | ± 0.25 mm | **Same as primary predicate** |
| **Horizontal speed** | Maximum Speed = 600 mm/sec<br>Minimum Speed = 1 mm/sec | Maximum Speed = 600 mm/sec<br>Minimum Speed = 1 mm/sec | Maximum Speed = 600 mm/sec<br>Minimum Speed = 1 mm/sec | Maximum Speed = 300 mm/sec<br>Minimum Speed = 1 mm/sec | **Same as primary predicate** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **Couch Vertical Range** | Minimum Height – 430 mm | Minimum Height – 430 mm | Minimum Height – 430 mm | 530 mm – STD Couch<br>430 mm – Noah HP Couch | **Same as primary predicate** |
| **Couch Horizontal Range** | 0-2413 mm for patient pallet<br>0-425 mm for sub pallet | 2413 mm | 2413 mm | With STD couch,<br>1,830mm—helical scan<br>1,860mm—Axial scan<br>With Noah couch,<br>1,900mm—helical scan<br>2,000mm—Axial scan | **Substantially equivalent;**<br>**The proposed Spectral CT Verida Family system introduces Noah RT-2 Couch to replace the Noah HP Couch.**<br>**Compared with Noah HP Couch, there's a sub pallet in Noah RT-2 Couch which provides the additional support to the patient pallet and can be motorized** |

| | Proposed Device<br>Spectral CT Verida Family | Primary Predicate Device<br>Spectral CT 7500 RT (K240844) | Reference Device<br>Spectral CT (K203020) | Reference Device<br>CT 5300 (K232491) | Note |
|---|---|---|---|---|---|
| | | | | | **moving.**<br>**The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **Scannable Surview Range** | w/o Bayonet Head Holder: 1940mm<br>w/ Bayonet Head Holder: 2190mm | 1940mm | 1940mm | 1940mm | **Substantially equivalent;**<br>**Additional scannable range is due to Bayonet Head holder plug in Couch head slot of the proposed Spectral CT Verida Family system.**<br>**The verification and validation** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **Scannable axial Range** | w/o Bayonet Head Holder: 2000mm<br>w/ Bayonet Head Holder: 2250 mm | 2000mm | 2000mm | 2000mm | **Substantially equivalent;**<br>**Additional scannable range is due to Bayonet Head holder plug in Couch head slot of the proposed Spectral CT Verida Family.**<br>**The verification and validation for this improvement were conducted and ensured no** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **new questions on safety and/or effectiveness will arise.** |
| **Scannable helical Range** | w/o Bayonet Head Holder: 1900mm<br>w/ Bayonet Head Holder: 2150mm | 1900mm | 1900mm | 1900mm | **Substantially equivalent;**<br>**Additional scannable range is due to Bayonet Head holder plug in Couch head slot of the proposed Spectral CT Verida Family system.**<br>**The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **will arise.** |
| **Acceleration** | 800 mm/Sec^2 | 800 mm/Sec^2 | 800 mm/Sec^2 | 800 mm/Sec^2 | **Same as primary predicate** |
| **Couch Max Load Capacity** | 675 lbs. (307 kg)<br>Utilizing Oncology flat tabletop optional accessory: 628 lbs. (285 kg) | 675 lbs. (307 kg)<br>Utilizing Oncology flat tabletop optional accessory: 628 lbs. (285 kg) | 675 lbs. (307 kg)<br>Utilizing Oncology flat tabletop optional accessory: 628 lbs. (285 kg) | 675 lbs. (307 kg)<br>Utilizing Oncology flat tabletop optional accessory: 628 lbs. (285 kg) | **Same as primary predicate** |
| **Couch accessories** | Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop, Bayonet Head holder | Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop | Infant Cradle, Paper roller, Varian Camera Adaptor, Oncology flat tabletop | Infant Cradle, Paper roller, Oncology flat tabletop | **Substantially equivalent;**<br>**The introduction of the Bayonet Head-holder on the Spectral CT Verida Family system is to allow for additional scannable range.**<br>**The verification and validation for this** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **GENERAL** | | | | | |
| **HOST Drives** | One 1TB SSD for the OS and Console Software plus one 7.68TB U.2 PCIe SSD for results | 256GB OS disk plus one 7.68TB PCIE<br>NVMe SSD | 256GB OS disk plus one 7.68TB PCIE<br>NVMe SSD | One 2TB SSD for the OS and Console Software. | **Substantially equivalent;**<br>**The proposed Spectral CT Verida Family system introduces an improvement to Host Drives (increased capacity of computer drives).**<br>**The verification and validation for this** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **Host Infrastructure** | Windows 10 | Windows 10 | Windows 10 | Windows 10 | **Same as primary predicate** |
| **CIRS Computers** | CIRS Rack that contains two HP Z8 servers.<br>Option for two additional HP Z8 Servers in the same rack. | CIRS Rack that contains two HP Z8 servers.<br>Option for two additional HP Z8 Servers in the same rack. | CIRS Rack that contains two HP Z8 servers.<br>Option for two additional HP Z8 Servers in the same rack. | CIRS run in the same PC with Host<br>in HP Z8 | **Same as primary predicate** |
| **CIRS CPUs** | In each HP Z8: Single Intel Xeon W9-3475X with 36 cores at 2.2GHz . | 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. | CPU1: Intel Xeon Silver 4214 processor 2.2 12C<br>CPU2: Intel Xeon Silver 4214 processor 2.2 12C | **Substantially equivalent;**<br>**The proposed Spectral CT Verida Family system introduces an improvement to CIRS CPUs** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | | | **(increased cores and higher frequency). The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **CIRS Drives** | In each HP Z8:<br>1TGB NVMe SSD for OS and CIRS software.<br>Two 2TB NVMe SSDs for raw data in CIRS S1 | In each HP Z8:<br>512GB NVMe SSD for OS and CIRS software.<br>Two 2TB NVMe SSDs for raw data in CIRS S1. | In each HP Z8:<br>512GB NVMe SSD for OS and CIRS software.<br>Two 2TB NVMe SSDs for raw data in CIRS S1. | One 2TB SSD for the results | **Substantially equivalent;**<br>**The proposed Spectral CT Verida Family system introduces an improvement to CIRS drives (increased size for OS and CIRS** |

| | Proposed Device<br>Spectral CT Verida Family | Primary Predicate Device<br>Spectral CT 7500 RT (K240844) | Reference Device<br>Spectral CT (K203020) | Reference Device<br>CT 5300 (K232491) | Note |
|---|---|---|---|---|---|
| | | | | | **software). The verification and validation for this improvement were conducted and ensured no new questions on safety and/or effectiveness will arise.** |
| **Interventional Controls** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **GENERAL (SPECTRAL)** | | | | | |
| **Technical Basis for collection of two CT Spectra:** | Dual Layer DMS (Spectral Detector) | Dual Layer DMS (Spectral Detector) | Dual Layer DMS (Spectral Detector) | Single Layer DMS | **Same as primary predicate** |
| **Spectral Base Images** | • Low-energy<br>• High-energy<br>• Photoelectric<br>• Compton Scatter | • Low-energy<br>• High-energy<br>• Photoelectric<br>• Compton Scatter | • Low-energy<br>• High-energy<br>• Photoelectric<br>• Compton Scatter | N/A | **Same as primary predicate** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **Spectral results available [kvp]** | • 100kvp<br>• 120kvp<br>• 140kvp | • 100kvp<br>• 120kvp<br>• 140kvp | • 100kvp<br>• 120kvp<br>• 140kvp | N/A | **Same as primary predicate** |
| **Spectral Results Images** | • Monoenergetic<br>• Materials Basis/Density Pairs, such as<br>  ○ I / H20<br>  ○ I / Ca<br>  ○ Ca / Uric Acid<br>• Effective Atomic Number<br>• Material Separation/ Differentiation<br>• Attenuation Curves<br>• Density Measurements/Visualization<br>• Reduction of Beam Hardening<br>• Reduction of Calcium Blooming<br>• Calcium Suppression Index<br>• Electron Density | • Monoenergetic<br>• Materials Basis/Density Pairs, such as<br>  ○ I / H20<br>  ○ I / Ca<br>  ○ Ca / Uric Acid<br>• Effective Atomic Number<br>• Material Separation/ Differentiation<br>• Attenuation Curves<br>• Density Measurements/Visualization<br>• Reduction of Beam Hardening<br>• Reduction of Calcium Blooming<br>• Calcium Suppression Index<br>• Electron Density<br>• Spectral results for Cardiac | • Monoenergetic<br>• Materials Basis/Density Pairs, such as<br>  ○ I / H20<br>  ○ I / Ca<br>  ○ Ca / Uric Acid<br>• Effective Atomic Number<br>• Material Separation/ Differentiation<br>• Attenuation Curves<br>• Density Measurements/Visualization<br>• Reduction of Beam Hardening<br>• Reduction of Calcium Blooming<br>• Calcium Suppression Index | N/A | **Same as primary predicate** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | • Spectral results for Cardiac | | • Electron Density<br>• Spectral results for Cardiac | | |
| **GENERAL (CONVENTIONAL AND SPECTRAL)** | | | | | |
| **Perfusion modes** | • Axial (increment of zero)<br>• Axial Gated (increment of zero)<br>• Axial Jog (two table positions)<br>• Helical | • Axial (increment of zero)<br>• Axial Gated (increment of zero)<br>• Axial Jog (two table positions)<br>• Helical | • Axial (increment of zero)<br>• Axial Gated (increment of zero)<br>• Axial Jog (two table positions)<br>• Helical | • Axial (increment of zero)<br>• Axial Jog (two table positions) | **Same as primary predicate** |
| **Virtual Tilt Viewer (VTV)** | Yes | Yes | Yes | Interventional Viewer | **Same as primary predicate** |
| **Interventional controls** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Pulmonary Gating** | Yes | Yes | Yes | N/A | **Same as primary predicate** |
| **Pulmo & 4DCT (Four-Dimension** | Yes | Yes | No | No | **Same as primary predicate** |

| | **Proposed Device**<br>**Spectral CT Verida Family** | **Primary Predicate Device**<br>**Spectral CT 7500 RT (K240844)** | **Reference Device**<br>**Spectral CT (K203020)** | **Reference Device**<br>**CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| **Computed Tomography)** | | | | | |
| **Dose Reduction** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Autovoice** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Localizer** | 3-axes laser localizer | 3-axes laser localizer | 3-axes laser localizer | N/A | **Same as primary predicate** |
| **Communication** | DICOM-3.0 | DICOM-3.0 | DICOM-3.0 | DICOM Compliance | **Same as primary predicate** |
| **Cardiac Retrospective Tagging option** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Cardiac reconstruction method** | Standard ECG Gated Reconstruction method<br>Precise Cardiac (optional feature) | Standard ECG Gated Reconstruction method<br>Precise Cardiac (optional feature) | Standard ECG Gated Reconstruction method<br>Motion Compensated Reconstruction (MCR) | Standard ECG Gated Reconstruction method<br>Precise Cardiac | **Same as primary predicate** |

| | **Proposed Device Spectral CT Verida Family** | **Primary Predicate Device Spectral CT 7500 RT (K240844)** | **Reference Device Spectral CT (K203020)** | **Reference Device CT 5300 (K232491)** | **Note** |
|---|---|---|---|---|---|
| | | | (optional feature) | (optional feature) | |
| **Cardiac Review and reporting** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Combine Images** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Test Injection Bolus Timing (also known as Time Lapse)** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **BolusPro Ultra** | Yes | Yes | Yes | No; CANOpen 4 Injector | **Same as primary predicate** |
| **CT Viewer** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **Reporting** | Yes | Yes | Yes | Yes | **Same as primary predicate** |
| **iDose4 (User selectable** | Yes | Yes | Yes | Yes | **Same as** |

| | Proposed Device<br>Spectral CT Verida Family | Primary Predicate Device<br>Spectral CT 7500 RT (K240844) | Reference Device<br>Spectral CT (K203020) | Reference Device<br>CT 5300 (K232491) | Note |
|---|---|---|---|---|---|
| **filters)** | | | | | **primary predicate** |
| **Spectral Precise Image** | Yes | No | No | No | **Substantially equivalent;**<br><br>**This algorithm is built off the CT 5300 (K232491) clearance that contains the Precise Image reconstruction algorithm. Please refer to the Device Description and Software sections, within this eSTAR submission, for more information.** |

The Spectral CT Verida Family also incorporates features previously cleared in reference devices such as the Spectral CT (K203020) and the CT5300 (K232491). These devices support performance claims for software reconstruction and image processing. However, they are not relied upon for substantial equivalence.

Based on the information provided above, the proposed Spectral CT Verida Family is considered substantially equivalent to the currently marketed primary predicate device, Spectral CT 7500 RT System (K240844), in terms of fundamental scientific technology.

PHILIPS

## SUMMARY OF NON- CLINICAL PERFORMANCE TESTING

Non-clinical performance testing has been performed on the proposed Spectral CT Verida Family 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).

Design verification planning and testing were conducted at the system level. The system is tested against the System Requirements Specifications (SRS) and the Sub-System Requirement Specifications (SSRS). System and sub-system verification activities demonstrate the system, or the sub-system meet the established system and sub-system level 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.
The detailed verification and validation results are provided in the full system verification and validation reports. Non-clinical design validation testing demonstrates that the proposed Spectral CT Verida Family system can be used as defined in its clinical workflow and intended use.

Summary of Spectral Precise Image IQ test report:

- Purpose:
  The bench performance testing aimed to evaluate the image quality and spectral accuracy of the Spectral Precise Image (SPI) feature. The objective was to demonstrate that SPI meets or exceeds the performance of the reference reconstruction method (iDose Level 0/FBP) in key image quality and spectral accuracy metrics.
- Methods:
  - Image Quality Metrics Testing
    - Metrics Evaluated: CT number linearity, image noise, uniformity, contrast-to-noise ratio (CNR), spatial resolution (MTF and SSP), low contrast resolution (visual), and image artifacts.
    - Phantoms Used: Verida system phantom, Gammex ACR phantom, Catphan phantom.
    - Test Design: Scans were performed in head, body, and cardiac modes, with varying kV, dose, and resolution settings. Reconstructions were performed using SPI at five AI levels and compared to iDose Level 0 using equivalent filters. Measurements were taken using identical raw data and reconstruction parameters.
    - Assessment: Visual and quantitative analysis of image quality metrics.
  - Spectral Accuracy Testing
    - Metrics Evaluated: Monochromatic energy (MonoE, HU), virtual non-contrast (VNC, HU), iodine density (mg/ml), iodine no water (mg/ml), iodine removed (HU), contrast-enhanced structures (HU), calcium suppression (HU), Z effective, electron density (%EDW), uric acid and uric acid removed (HU).
    - Phantoms Used: Gammex 472, Gammex 467, Gammex ACR, 20cm MECT phantom.
    - Test Design: Scans performed in head, body, and cardiac modes, with approximately 35 scans and 400 reconstructions. Measurements were made by drawing ROIs on phantom rods and comparing SPI and iDose Level 0 results.
    - Assessment: Accuracy and noise reduction were measured, with tolerances referenced from system requirements.
  - Results:
    - Image Quality Metrics
      - SPI improved some image quality metrics (notably image noise and CNR) and preserved others (CT number linearity, uniformity, spatial resolution, low contrast resolution).
      - No new or unexpected artifacts were observed.

        - SPI preserved low contrast resolution.
    - Spectral Accuracy
        - SPI preserved the accuracy of all tested spectral results compared to iDose Level 0, with differences well within system requirement tolerances.
        - For results with noise blending (e.g., MonoE), SPI reduced image noise compared to iDose Level 0.
        - For Z Effective and Electron Density, differences between SPI and iDose Level 0 were negligible and much smaller than tolerance limits.
        - For Uric Acid and Uric Acid Removed, differences were within [-1HU, 1HU], far below the minimum tolerance of ±20HU.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the proposed Spectral CT Verida Family 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 Verida Family system is substantially equivalent to the currently marketed primary predicate device, Spectral CT 7500 RT system (K240844), in terms of safety and effectiveness

## SUMMARY OF CLINICAL TESTING

Summary of Spectral Precise Image Clinical Study Report:

The clinical study was conducted per FDA guidance *"Clinical Performance Studies for Diagnostic Imaging Devices"* and *"Best Practices for Conducting and Reporting Clinical Studies in 510(k)s."*

- Purpose:
  The purpose of the study was to evaluate the Image Quality (IQ), and diagnostic confidence of Spectral Precise Image for CT 7700 Scanner as compared with iDose4 as a standard-of-care reference
- Study Overview:
    - Title: Clinical study for Spectral Precise Image (SPI) algorithm
    - Device: Philips Spectral CT Verida Family
    - Protocol ID: SEF-2024-300450, Version 6.0
    - Sponsor: Philips Medical Systems Technologies Ltd.
    - Sites: Hospital of the University of Pennsylvania (UPenn), Albert Einstein College of Medicine/Montefiore Medical Center
    - Study Design: Retrospective, multi-site, controlled, blinded, non-inferiority clinical investigation
    - Population: Adults aged >22 years, scanned using Philips Spectral CT (K203020)
    - Sample Size: 147 scans (Head: 42, Body: 42, Cardiac: 42, Chest: 21)
    - Initiation Date: 15-JUL-2025
    - Completion Date: 30-SEP-2025
- Methods:
    - Data: Previously acquired, anonymized clinical CT data.
    - Reconstructions: Each scan reconstructed with both iDose$^4$ and SPI for:
        - Conventional images

        - Spectral MonoE images (MonoE 70keV for Cardiac/Body, 66keV for Head)
    - Readers: U.S. board-certified radiologists/cardiologists, blinded to reconstruction method.
    - Assessment: Images presented side-by-side, randomized order; 5-point Likert scale for image quality and diagnostic confidence.
    - Endpoints:
        - Co-primary: Non-inferiority of SPI vs. iDose$^4$ for image quality and diagnostic confidence in both conventional and spectral images.
        - Secondary: Comparison of SPI spectral images to iDose$^4$ conventional images, performance in chest high-resolution scans, success rate, and reader agreement.
- Conclusion
    - SPI is non-inferior to iDose$^4$ for image quality in both conventional and spectral images across all anatomical regions tested.
    - SPI offers improved image texture, and higher reader agreement, in clinical image reconstruction.
    - The study supports the robust clinical performance and substantial equivalence of SPI to the predicate device.

The clinical investigation demonstrates that the Spectral Precise Image (SPI) algorithm for the proposed Spectral CT Verida Family system provides image quality that is at least as good as, the standard iDose$^4$ reconstruction. SPI is preferred by readers for image texture and achieves high consistency and success rates across all evaluated anatomical regions and image types. No new safety issues were identified.

## SUMMARY OF RISK ANALYSIS

A risk analysis was performed for Spectral CT Verida Family system in accordance with ISO 14971 and the Philips Quality Management System. Identified hazards and hazardous situations associated with the software were evaluated, and appropriate risk control measures were implemented to mitigate identified risks.

Verification and validation testing demonstrated that all defined risk control measures were correctly implemented and effective, and that all software requirements and specifications met their predefined acceptance criteria. Residual risks were evaluated and determined to be acceptable based on a benefit-risk assessment consistent with the device's intended use.

The results of software verification and validation activities support that Spectral CT Verida Family system performs as intended and does not introduce new questions of safety or effectiveness when compared to the predicate device. The testing conducted is sufficient to support the determination of substantial equivalence.

## SUMMARY OF CYBERSECURITY

The cybersecurity testing for the Spectral CT Verida Family system was conducted in accordance with FDA-recognized consensus standards and specifically aligns with the following FDA guidance:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (FDA, June 27, 2025)
- Additional relevant FDA software and risk management guidance documents.

The cybersecurity testing included:

- A formal risk assessment (Product Security Risk Assessment, Threat Model Analysis) to identify potential cybersecurity threats and vulnerabilities.
- Risk mitigations were identified, implemented, and traced to specific security controls and verification activities.
- System Verification Traceability Matrix documents traceability between security requirements, risk mitigations, and verification test reports.
- Verification testing covered security and privacy requirements at both system and sub-system levels.
- Vulnerability scanning and penetration testing (SCoE Pentest Report, Vulnerability Scan Report) were performed to identify and address potential security weaknesses.
- Secure code analysis to identify and remediate software vulnerabilities at the source code level.
- Secure code analysis to identify and remediate software vulnerabilities at the source code level.
- Security Test Reports and Product Security Evaluation Reports summarize the results of all cybersecurity testing activities.
- Testing included verification of security controls, validation of risk mitigations, and confirmation that the system meets all cybersecurity requirements.
- Any unresolved cybersecurity vulnerabilities or anomalies are fully documented, controlled, and tracked within the Design History File (DHF).
- At the time of submission, only one known cybersecurity vulnerability remained open, which was determined not to impact patient safety, clinical performance, or intended use. A corrective action was planned prior to customer release.
- All cybersecurity testing, findings, and mitigations are documented and traceable to requirements and risk assessments.
- The submission includes a Software Bill of Materials (SBOM) and Manufacturer Disclosure Statement for Medical Device Security (MDS2) for transparency

Conclusion

The cybersecurity testing for the Spectral CT Verida Family system was comprehensive and aligned with FDA guidance. It included risk assessments, verification of security controls, vulnerability scanning, penetration testing, secure code analysis, and thorough documentation of all findings and mitigations. All known issues were documented and managed, with no unresolved vulnerabilities impacting safety or effectiveness at the time of submission.

## SUMMARY OF BIOCOMPATIBILITY TESTING

The patient-contacting materials of the Spectral CT Verida Family were evaluated in accordance with ISO 10993-1:2018 using a risk-based approach.

The device includes patient-contacting components that contact intact skin for limited duration (<24 hours). The patient-contacting materials used in the Verida system are addressed in Attachment G of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and pose a very low biocompatibility risk because they have a long history of safe use in legally marketed medical devices that contact intact skin.

Based on the above, the Spectral CT Verida Family meets the biocompatibility requirements of ISO 10993-1, and no additional biocompatibility testing is required.