June 27, 2025

Philips Medical Systems Nederland B.V.
℅ Yael Curtz
Regulatory Affairs Manager and Site Lead
Advanced Technology Center, Building 34, MATAM
HAIFA, 3100202
ISRAEL

Re: K250648
Trade/Device Name: Philips iCT CT system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: February 27, 2025
Received: May 20, 2025

Dear Yael Curtz:

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,

FDA Digitally signed by Gabriela M. Rodal -S 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)*
K250648

Device Name
Philips iCT CT system

Indications for Use *(Describe)*
The Philips iCT CT systems is a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories. The iCT is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

These scanners are intended to be used for diagnostic imaging and for low dose CT lung cancer screening for the early detection of lung nodules that may represent cancer*. The screening must be performed within the established inclusion criteria of programs / protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K250648
510(k) Summary

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

Date Prepared	**March 4th, 2025**	
Manufacturer	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC BEST The Netherlands	
Establishment Registration Number	3015777306	
Primary Contact Person	Ms. Yael Curtz Regulatory Affairs Team Lead Phone: +972-54-7282285 E-mail:yael.curtz@philips.com	
Secondary Contact Person	Carmit Shmuel Regulatory Affairs Manager and Site Lead Phone: +972-54-2109054 E-mail: carmit.shmuel@philips.com	
Subject Device	**Trade Name**	Philips iCT CT System
	Common Name	iCT System
	Classification Name	System, X-Ray, Tomography, Computed
	Classification Regulation	21 CFR 892.1750
	Classification Panel	Radiology
	Device Class	II
	Product Code	JAK
Predicate Device	**Trade Name**	Philips iCT CT System
	Manufacturer	Philips Medical Systems (Cleveland), Inc.
	510(k) Clearance	K162838
	Classification Regulation	21 CFR 892.1750
	Classification Panel	Radiology
	Device Class	II
	Product Code	JAK

Device Description

The Philips iCT CT System is a whole-body computed tomography (CT) X-ray system designed for diagnostic imaging. It features a continuously rotating X-ray tube and multi-slice detector gantry, enabling the acquisition of X-ray transmission data from multiple angles and planes. The system reconstructs these data into cross-sectional images using advanced image reconstruction algorithms, supporting a wide range of clinical applications.

The system consists of a gantry, which houses the rotating X-ray tube, detector array, and key imaging subsystems; a patient support couch, which moves the patient through the gantry bore in synchronization with the scan and is available in multiple configurations; an operator console, which serves as the primary user interface for system controls, image processing, and data management; and a Data Measurement System (DMS), which captures X-ray attenuation data to support high-quality image reconstruction.

The Philips iCT CT System maintains the same intended use and fundamental operating principles as its legally marketed predicate device (Philips iCT CT System, K162838) while incorporating hardware

and software enhancements to improve system performance, cybersecurity, and usability. These updates do not alter the device's core functionality, imaging capabilities, or clinical workflow.

Indications for Use Statement

The Philips iCT CT systems is a Computed Tomography X-Ray System intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories. The iCT is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages.

These scanners are intended to be used for diagnostic imaging and 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.

Indications for Use Comparison to Predicate

The proposed and predicate devices share the same intended use, target patient population, and technological principles. While the subject device includes hardware and software updates as described above, all modifications were validated to ensure they do not impact core performance or introduce new safety concerns. The enhancements support system reliability, cybersecurity, and image quality.

Technological Comparison / Modifications

The Philips iCT CT System shares the same technological characteristics as the legally marketed predicate device, Philips iCT CT System (K162838). Both systems employ a continuously rotating X-ray tube and multi-slice detector array for image acquisition, with computer-assisted reconstruction of cross-sectional images of the body. The principle of operation, energy source, and control mechanisms remain unchanged between the two devices.

Below is a high-level overview of the Technological Characteristic Comparison between the subject and predicate device:

	Subject Device Philips iCT CT System	**Predicate Device Philips iCT CT System (K162838)**	**Comparison**
Indications for Use	Same	Same	
Design and Fundamental Scientific Technology			
Application	Head/Body	Same	
Scan regime	Continuous Rotation	Same	
Scan modes	Surview Helical Axial	Same	
Spatial Resolution	Ultra-high mode 24+/-2 lp/cm High mode 16+/-2 lp/cm	Same	

	Standard mode 13+/-2 lp/cm		
Low contrast resolution	iCT: 5 mm +/-0.3% 14mGy CTDIvol 3 mm +/- 0.3% 25 mGy (20 cm Catphan phantom, 10 mm slice thickness) CTDIvol iCT SP: 4 mm +/- 0.3% 16.4 mGy CTDIvol (20 cm Catphan phantom, 10 mm slice thickness)	Same	
Noise	0.27% at 120kV, 250 mAs (10mm slice thickness)	Same	
Reconstruction speed	33 images/sec	Same	
Image Matrix	512^2, 768^2, 1024^2	Same	
Display	1024x1280	Same	
Communication	DICOM – 3.0	Same	
Detectors			
Type	Nano Panel Prism	Same	
Material	Ceramic scintillator	Same	
Slices	iCT configuration: 256 iCT SP configuration: 128	Same	
Coverage	iCT configuration: 8 cm iCT SP configuration: 4 cm	Same	
Collimation	iCT configuration: 128 x 0.625 mm 112 x 0.625 mm 96 x 0.625 mm 64 x 0.625 mm 32 x 0.625 mm 20 x 0.625 mm 16 x 0.625 mm 8 x 0.625 mm 4 x 0.625 mm 2 x 0.625 mm 64 x 1.25 mm 32 x 1.25 mm iCT SP configuration: 64 x 0.625 mm 32 x 0.625 mm 20 x 0.625 mm 16 x 0.625 mm 8 x 0.625 mm 4 x 0.625 mm 2 x 0.625 mm 64 x 1.25 mm 32 x 1.25 mm	Same	
Scan field	50 -500 mm continuous 25 - 250mm ultra-high resolution	Same	
Gantry			
Bore size	700 mm	Same	

Focus-isocenter distance	570 mm	Same	
Focus-detector distance	1040mm	Same	
Rotation times	0.3, 0.33, 0.375, 0.4, 0.5, 0.75, 1.0, 1.5 seconds for full 360° scans; 0.2 for partial angle 240° scans. (Optional - 0.27 seconds for full 360° scans; 0.18 seconds for partial angle 240° scans)	Same	
Gantry and Couch covers color	**White**	**Mushroom**	**Aesthetic Only**
Generator and Tube Performance			
Power	100kW (120kW optional)	Same	
kV Setting	80, 100, 120, 140	Same	
mA Range	10-830 (1mA steps), optional 10-1,000)	Same	
Focal spot – Smart Focal Spot	small 0.6 x 0.7; large 1.1 x 1.2	Same	
Couch			
Couch	Standard Bariatric Extended (aka Long)	Same	
Patient table scan range	Standard: 1750 mm Bariatric: 1750 mm Long: 2100 mm	Same	
Table Z-position accuracy	Standard: +/- 0.25 mm Bariatric: +/- 0.25 mm Long: +/- 0.25 mm	Same	
Table longitudinal speed	Standard: 0.5 – 185 mm/sec Bariatric: 0.5 – 185 mm/sec Long: 0.5 – 185 mm/sec	Same	
Table maximum load capacity	Standard: 450 lbs. (204kg) Bariatric: 650 lbs. (405kg) Long: 450 lbs. (204kg)	Same	
General			
CIRS Computers	**Windows 10**	**Windows 7**	**Security/Compatibility Improvement**
Interventional Controls	Support two types of Interventional Exams: Basic Interventional and Advanced Interventional (also called CCT)	Same	
Harmonized Phantom Kit	**Available**	**Not Available**	**Upgraded Calibration Kit**
Security Updates	**Enhanced (RBAC, encryption, audit)**	**Basic**	**Updated**
Software Features			
Head scan Image Quality Improvement	**Included**	**Standard Head Scan Imaging**	**Algorithmic Improvement**

(Optional Feature) Concurrent Recon in Iterative Model Reconstruction (IMR)	**Included**	**Sequential Reconstruction of iDose/BP**	**Workflow Enhancement**
Size Specific Dose Estimate (SSDE)	**Included**	**Not Available**	**Automated calculation; Informational only**

The proposed Philips iCT CT System hardware and software modifications are detailed as follows:

- **Harmonized Phantom Kit**: Updated calibration phantoms with standardized dimensions and materials (PMMA) for consistency across platforms. These phantoms replace legacy versions and are used in acceptance, constancy, and quality assurance testing.
- **White Covers**: Aesthetic color change of the gantry and couch covers from Mushroom to White
- **Operating System Upgrade**: Software upgrade from Windows 7 to Windows 10 to meet current cybersecurity and compatibility standards.
- **Security Enhancements**: Implementation of software hardening, vulnerability mitigation, access control, and encryption.
- **Head Scan Image Quality Enhancement**: Optimization of the reconstruction algorithm to improve image homogeneity and sharpness.
- **Concurrent Reconstruction (Optional):** An optional feature enabling concurrent iDose/BP reconstruction on the IMR server for improved throughput without altering imaging output.
- **Size Specific Dose Estimate (SSDE) Display**: Addition of SSDE dose metric display to improve dose awareness; calculated using existing system measurements and does not affect scan output.

These modifications do not change the intended use, fundamental scientific technology, or safety and effectiveness profile of the system. The updates have been verified and validated to ensure they do not impact safety, effectiveness, or the system's intended use.

A comprehensive evaluation was conducted to confirm that the modifications introduced in the Philips iCT CT System do not raise new questions of safety or effectiveness. This included system-level verification and validation, requirements-based regression testing, usability validation (IEC 62366-1), biocompatibility assessment (ISO 10993), electromagnetic compatibility and electrical safety testing (IEC 60601-1 and IEC 60601-1-2), and a cybersecurity evaluation aligned with FDA's 2023 guidance. Risk management activities were performed in accordance with ISO 14971, and software lifecycle documentation followed IEC 62304.

Collectively, these activities confirm that the system modifications are safe, effective, and compliant with FDA-recognized consensus standards. Therefore, based on the technological comparison, risk analysis, and non-clinical testing results, the modified Philips iCT CT System is substantially equivalent to the predicate device.

Non-Clinical / Clinical Test Summary

The non-clinical testing strategy followed an established framework to verify that all system changes, both hardware and software, did not introduce new risks and remain in compliance with regulatory requirements. No clinical testing was required, as the intended use, core imaging algorithms, and diagnostic claims remain unchanged from the predicate (K162838).

Verification Testing

Requirements-based testing was performed to verify that all modified system components met their respective requirements through structured test execution. Regression testing confirmed that

modifications did not impact existing system functionality. The following verification activities were conducted to ensure compliance with regulatory and safety expectations:

- Cybersecurity testing, including penetration testing, vulnerability assessment, and access control validation, was performed per *FDA's Cybersecurity in Medical Devices* Guidance (2023).
- Static code analysis and software review were conducted to confirm adherence to secure coding practices.
- Electromagnetic Compatibility (EMC) testing was performed in accordance with *IEC 60601-1-2*.
- Electrical safety testing was conducted per *IEC 60601-1* and *IEC 60601-2-44*.
- Biocompatibility evaluation followed *ISO 10993* to confirm safety of unchanged patient-contacting materials.

Validation Testing

Validation activities confirmed that system updates aligned with intended use and user needs. Testing included:

- Usability testing in accordance with IEC 62366-1, evaluating user interaction and workflow.
- System-level validation under simulated clinical conditions, confirming functionality of modified hardware and software.
- Software validation ensuring reliable system performance after updates, including:
    - Operating system transition
    - Cybersecurity enhancements

Performance Testing

To support the modifications in the Philips iCT CT System, a comprehensive non-clinical performance testing strategy was executed. Testing included both bench testing and phantom-based evaluations, addressing software, imaging, usability, and cybersecurity enhancements.

Testing activities included:

- Automated Image Quality (IQ) Testing using standard phantoms to assess CT number accuracy, contrast-to-noise ratio (CNR), uniformity, modulation transfer function (MTF), slice width accuracy, and noise characteristics.
- Phantom Testing using anthropomorphic head phantoms to evaluate head image quality enhancements, specifically improvements in homogeneity and sharpness near bone-brain interfaces.
- Traceability to system requirements was maintained across all testing, with test results documented in the system verification report and traceability matrices.

These tests confirmed the modified device performs equivalently to the predicate and supports the substantial equivalence determination.

Compliance with FDA-Recognized Consensus Standards

Testing protocols ensured compliance with the following FDA-recognized standards:

- IEC 60601-1: Edition 3.2 (2020-08) – FDA Recognition Number: 19-49, *General Requirements for Basic Safety and Essential Performance*
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] – FDA Recognition Number: 19-36, *Electromagnetic Compatibility (EMC) – Requirements and Tests*
- IEC 60601-1-3: Edition 2.2 (2021-01) – FDA Recognition Number: 12-336, *Radiation Protection in Diagnostic X-ray Equipment*
- IEC 60601-2-44: Edition 3.0 (2017-06) – FDA Recognition Number: 12-309, *Particular Requirements for the Safety of X-ray Equipment for Computed Tomography*
- IEC 62366-1:2015+AMD1:2020 (Consolidated Text) – FDA Recognition Number: 5-129. *Application of Usability Engineering to Medical Devices*

Conclusion

All verification and validation activities were successfully completed in accordance with Philips' quality system. Testing confirmed that the Philips iCT CT System continues to meet its intended use and satisfies all applicable user, performance, and safety requirements. The results demonstrated that the modifications do not introduce new risks or adversely affect the safety or effectiveness of the system. This comprehensive non-clinical evaluation supports the determination of substantial equivalence to the predicate device under 21 CFR 807.92(b).