July 10, 2026

Philips Medical Systems B.V.
% Jeroen De Schrijver
Regulatory Affairs Manager
Veenpluis 6
Bldg. Qp
Best, Noord-Brabant 5684PC
NETHERLANDS

Re: K253670
Trade/Device Name: SmartCT (R3.0 (L10))
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAK, LLZ
Dated: June 11, 2026
Received: June 11, 2026

Dear Jeroen De Schrijver:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253670

Please provide the device trade name(s).

SmartCT (R3.0 (L10))

Please provide your Indications for Use below.

SmartCT assists physicians during vascular and non-vascular procedures, with diagnosis, treatment planning, interventional procedures and treatment follow-up by creating 3D views from sets of 2D images created during rotational acquisitions.
SmartCT provides high-speed and high-resolution 3D visualizations of vasculature, hemorrhages, soft tissue and bone structures.

SmartCT provides live image guidance for navigating endovascular devices through vascular structures anywhere in the body.

SmartCT helps to assess anatomical information intra-procedurally, such as the estimate of a vessel or lesion size, diameter or volume, and anatomical distances between relevant structures.

SmartCT is intended to be used for human patients that have been elected for the procedures as described in these Indications for Use.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

The 510(k) Summary is given in the below pages.

510(k) Summary for K253670

This 510(k) Summary is prepared in accordance with 21 CFR *807.92* and provides information supporting FDA's determination of substantial equivalence.

Date Prepared:	**June 8, 2026**	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Jeroen de Schrijver Regulatory Affairs Manager, IGT-S Fixed Phone: +1 8863334246 E-Mail: jeroen.de.schrijver@philips.com	
Secondary Contact Person:	Daniela Zaczek Director of Regulatory Affairs, IGT-S Fixed Phone: +1 8863334246 E-mail: daniela.zaczek@philips.com	
Device:	Trade Name:	**SmartCT (R3.0 (L 10))**
	Common Name	Interventional Fluoroscopic X-ray System
	Classification Name: Classification Regulation: Classification Panel: Device Class: Product Code:	Image-intensified fluoroscopy x-ray system 21CFR §892.1650 Radiology Class II Primary Code: OWB Subsequent Codes: JAK, LLZ
Predicate Device:	Trade Name: Manufacturer: 510(k) Clearance: Common Name Classification Name:	*SmartCT R1.0* Philips Medical Systems Nederland B.V. K201583 (cleared on 9 February 2021) Interventional Fluoroscopic X-ray System Image-intensified fluoroscopy x-ray system

Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: OWB Subsequent Code: JAK, LLZ

Device description:

SmartCT is a 3D image visualization and analysis software product (Interventional Tool) intended to provide fast and high-resolution 3D visualization of vasculature, hemorrhages, soft tissue and bone structures, thereby helping the physician to identify pathologies and supporting the physician to define and plan the intervention strategy.

SmartCT runs on a software platform called the *Interventional Workspot*, and is intended to be used with a Philips Interventional X-Ray System.

SmartCT supports 3D Rotational Angiography (3DRA), Cone Beam CT (CBCT) and VasoCT acquisition protocols, and it includes 3D roadmap functionality. The CBCT and VasoCT protocols are only available for the 20" detector of the Interventional X-Ray system. The 3DRA protocols are available for all detectors.

The 3DRA protocols are available with *SmartCT Angio*, the CBCT protocols with *SmartCT Soft Tissue* and the VasoCT protocols with *SmartCT Vaso*. The 3D roadmap functionality (*SmartCT Roadmap*) comes in combination with *SmartCT Angio*, *SmartCT Soft Tissue* or *SmartCT Vaso*.

SmartCT includes filters to improve the image quality of the reconstruction by reducing the noise caused by metal objects or other objects that absorb high levels of X-ray radiation.

SmartCT provides overlays of live 2D fluoroscopic images with a 3D reconstruction of the vessel tree.

SmartCT offers tools to manually measure sizes and volumes of anatomical structures such as lesions, aneurysms or vessels. It also offers a vessel analysis tool that provides automatic measurements of the diameter of a segmented vessel.

SmartCT can be controlled from both the control room and the examination room.

SmartCT provides workflow guidance to support the physician in the workflow of acquiring and processing 3D images.

SmartCT does not display Hounsfield Unit (HU) values and does not provide HU-calibrated quantitative radiodensity output.

Indications for Use:

SmartCT assists physicians during vascular and non-vascular procedures, with diagnosis, treatment planning, interventional procedures and treatment follow-up by creating 3D views from sets of 2D images created during rotational acquisitions.

SmartCT provides high-speed and high-resolution 3D visualizations of vasculature, hemorrhages, soft tissue and bone structures.

SmartCT provides live image guidance for navigating endovascular devices through vascular structures anywhere in the body.

SmartCT helps to assess anatomical information intra-procedurally, such as the estimate of a vessel or lesion size, diameter or volume, and anatomical distances between relevant structures.

SmartCT is intended to be used for human patients that have been elected for the procedures as described in these Indications for Use.

Note: SmartCT is intended for intraprocedural qualitative visualization. CBCT and VasoCT scans are not designed or validated for precise quantitative radiodensity assessment. The intended use does not rely on diagnostic HU values, and **SmartCT** does not conform to the diagnostic HU scale, nor is such conformance applicable to its intended clinical function.

The indications for use of **SmartCT R3.0 (L 10)** are the same as the indications for use of the currently marketed predicate device *SmartCT R1.0.* Based on the information provided below, **SmartCT R3.0 (L 10)** is considered substantially equivalent to the currently marketed and predicate device S*martCT R1.0* in terms of Indications for Use.

Technological characteristics:

SmartCT R3.0 (L 10) has similar technological characteristics compared to the predicate device. Neither the subject device nor the predicate device displays HU values or provides HU-calibrated quantitative radiodensity output; accordingly, diagnostic HU-scale conformance is not a technological feature of the devices' intended clinical function.

Similar features are used in the predicate and subject device, with exception of the following major modifications implemented in **SmartCT R3.0 (L 10)**:

Improved image quality for neuro CBCT imaging (NeuroHQ)

SmartCT R3.0 (L 10) provides support for updated neuro 3D acquisition protocols, which are added to the Azurion interventional X-ray system. The 3D acquisition protocols are:

- Updated: Circular CBCT scan, using a circular trajectory;
- Added: Helical CBCT scan, using a dual axis rotational trajectory; and
- Added: Dual Phase CBCT scan, using two subsequent circular CBCT scans for neuro within the same acquisition protocol.

SmartCT R3.0 (L 10) introduces an updated 3D reconstruction algorithm for the updated 3D acquisition protocols. It includes filters to reduce cone beam, bone beam, system vibration, ring and table scattering artifacts. Next to this it offers the following optional secondary 3D reconstruction filters to reduce typical neuro procedure artifacts on:

- Metallic objects (e.g., endovascular devices such as coils)
- Patient head motion (to compensate for patient motion during the CBCT acquisition)

Extension of interventional X-ray System compatibility

Compared to *SmartCT R1.0*, **SmartCT R3.0 (L 10)** extends compatibility with the latest available Interventional X-ray Systems:

- Azurion R2.2, Azurion R3.0 and Azurion R3.1
- Updated acquisition protocols are introduced with their corresponding calibration protocols. By installing the NeuroHQ acquisition protocols and performing the corresponding calibrations.

Reconstruction algorithm

For NeuroHQ imaging, the updated 3D reconstruction algorithm implemented in **SmartCT R3.0 (L 10)** is based on an analytical, filtered back-projection–type algorithm. The method is physics-based and models X-ray attenuation and acquisition geometry to reconstruct volumetric images from rotational projection

data, supporting both circular and helical acquisition trajectories. The reconstruction process consists of deterministic steps including preprocessing of projection data, frequency-domain filtering, and back-projection into a 3D volume. In addition to the primary 3D reconstruction, the **SmartCT R3.0 (L 10)** provides optional secondary reconstruction workflows for image quality improvement (e.g., reduction of artifacts from metallic objects and patient head motion), which may involve multiple reconstruction passes using repeated forward- and back-projection operations.

Warning: Images created by the viewing application are artificially reconstructed images and the selected viewing settings may affect the image visualization. Diagnosis or treatment cannot be solely based on these images. All findings, decisions, and diagnoses must be confirmed by the use of conventional (2D) X-ray imaging.

The differences between **SmartCT R3.0 (L 10)** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided, **SmartCT R3.0 (L 10)** is considered substantially equivalent to the currently marketed and predicate device *SmartCT R1.0* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **SmartCT R3.0 (L 10)** and demonstrates compliance with the following FDA recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.1, 2020-06). FDA/CDRH recognition number 5-129.
- IEC 82304-1 Health software – Part 1: General requirements for product safety (Edition 1.0 2016-10), FDA/CDRH recognition number 13-97.
- ISO 14971 Medical devices – Application of risk management to medical devices (Third Edition 2019-12). FDA/CDRH recognition number 5-125.
- ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (Fourth edition 2021-07). FDA/CDRH recognition number 5-134.
- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer (First edition 2021-04 Corrected version 2021-12). FDA/CDRH recognition number 5-135.
- ANSI UL 2900-1, Standard For Safety, Standard For Software Cybersecurity Network-Connectable Products, Part 1: General Requirements (First Edition, 2017). FDA/CDRH recognition number 13-96
- ANSI UL 2900-2-1, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
- NEMA PS 3.1 - 3.20 2024e, Digital Imaging and Communications in Medicine (DICOM). FDA/CDRH recognition number 12-363
- IEC 80001-1 Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities (Edition 1.0, 2010-10). FDA/CDRH recognition number 13-38
- IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle. FDA/CDRH recognition number 13-122

Software verification testing of the functional and non-functional requirements as well as performance, reliability and safety has been successfully performed to verify that all the requirements of System Requirements Specification as well as the safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements and mitigations have been implemented.

Bench testing was conducted to evaluate image quality and reconstruction performance characteristics, including uniformity, geometrical accuracy,

linearity, low-contrast resolution, high-contrast resolution, spatial resolution, noise, contrast-to-noise ratio, modulation transfer function, and artefact reduction performance. The acceptance criteria for these tests were based on predefined quantitative performance specifications, successful calibration and verification activities, confidence interval thresholds, or comparative benchmark constancy analyses against the predicate system, as applicable.

Non-clinical validation testing has been performed to validate that **SmartCT R3.0 (L 10)** conforms to the intended use, claims, user needs, effectiveness of safety measures and instructions for use. The validation consisted of the following activities:

- A simulated use design validation was undertaken with participants who fulfilled the intended user profile. The participants executed validation protocols in the form of a clinical workflow to validate user needs, intended use and claims. In addition, simulated use validation for service workflows was performed by a service engineer to validate specific service-related user needs. Results demonstrated that all executed simulated use validation protocols were passed.

- A comparative reader assessment using a Likert-scale evaluation was performed by U.S. board-certified physicians to validate the NeuroHQ image quality and marketing claims. Results demonstrated that the Image Quality was substantially equivalent, and commercial claims were successfully validated.

- Usability validation was performed with representative clinical users (both physicians and nurse/technicians) in a simulated use environment. **SmartCT R3.0 (L 10)** was found to be safe and effective for the intended use, users and use environment.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **SmartCT R3.0 (L 10)**:

- complies with the international and FDA-recognized consensus standards, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, **SmartCT R3.0 (L 10)** is substantially equivalent to the predicate device *SmartCT R1.0* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

No prospective clinical investigation involving the testing of new patients was conducted for **SmartCT R3.0 (L 10)**. Substantial equivalence to the currently marketed predicate device, *SmartCT R1.0*, was demonstrated based on indications for use, technological characteristics, non-clinical performance testing, and safety and effectiveness considerations.

Previously acquired clinical image data from adult patients undergoing representative neuro-interventional procedures were used in a comparative reader assessment and were relied upon to support the determination of substantial equivalence for applicable device claims and features. The retrospectively collected datasets originated from clinical sites in the United States, Asia, and Europe and included procedures such as cerebral aneurysm embolization, mechanical thrombectomy for vessel occlusions, trans-arterial embolization, and carotid artery stenting. As the evaluation was performed using previously acquired clinical image data rather than prospective patient testing, assessment of device-related adverse events or complications was not applicable.

Substantial Equivalence Conclusion:

SmartCT R3.0 (L 10) is substantially equivalent to the currently marketed predicate device *SmartCT R1.0* (K201583) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that **SmartCT R3.0 (L 10)** complies with the requirements specified in the international and FDA-recognized consensus standards and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.