March 5, 2026

Philips Medical Systems Nederland B.V.
Elena Aizik
Regulatory Affairs Manager
Veenpluis 6
5684 Pc
Best,
Netherlands

Re: K260169
Trade/Device Name: AV Cardiac CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK, QIH
Dated: January 20, 2026
Received: January 20, 2026

Dear Elena Aizik:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software 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

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.	K260169

Please provide the device trade name(s).

AV Cardiac CT

Please provide your Indications for Use below.

The AV Cardiac CT applications are intended to assist the user in viewing, processing, analysis of CT datasets and in preparation of cardiac interventions.

The CT Coronary Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of coronary artery anatomy for patients with suspected or diagnosed cardiac disease including coronary artery disease.

The CT Functional Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of heart anatomy and function, for patients with suspected or diagnosed cardiac disease.

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

Philips Medical Systems' AV Cardiac CT

Company's Name and Address	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
Contact Person	Elena Aizik Regulatory Affairs Manager MATAM building 34, Haifa, 3100202, Israel +972543162610 elena.aizik@philips.com
Date	March 4, 2026
Device Trade name	AV Cardiac CT
Classification Name	System, x-ray, tomography, computed
Primary Product Code	JAK
Secondary Product Code	QIH
Classification	21 CFR 892.1750, 21 CFR 892.2050
Primary Predicate Device	Philips Medical Systems' Spectral CT Applications (K150665)
Reference Device	GE Medical Systems' CardIQ Suite (K213725)
Device Description	AV Cardiac CT is a standalone, software-only medical device intended for advanced visualization, post-processing, and analysis of cardiac computed tomography (CT) datasets. The software assists qualified medical professionals in viewing and analyzing gated cardiac CT images to support diagnosis and follow-up, as well as review of information in the context of preparation for cardiac interventions. AV Cardiac CT includes CT Coronary Analysis and CT Functional Analysis applications. The device is intended for use in the analysis of coronary artery anatomy and cardiac function in patients with suspected or diagnosed coronary artery disease, using gated cardiac CT data, including conventional and spectral acquisitions. The device provides visualization, measurement, and post-processing tools that enable review of quantitative information derived from CT images. AV Cardiac CT does not perform automated diagnosis, clinical decision-making, or treatment recommendations. All measurements and visualizations are intended to support physician review; the final clinical interpretation and procedural decisions remain the responsibility of the qualified healthcare professional. As part of the CT Coronary Analysis application, AV Cardiac CT provides a dedicated planning workflow - planning module - that organizes existing visualization and measurement tools—such as vessel length, diameter, and approximate C-arm angulation—to support pre-procedural review, such as for percutaneous coronary intervention (PCI). The workflow enables users to review relevant findings with corresponding anatomical images, determine proximal and distal landing zones, and save or export measurement values. The planning workflow does not automate device selection or treatment decisions and is intended to assist review and preparation, with physician judgment retained. Key Features and Algorithms AV Cardiac CT provides basic viewing, processing, and measurement functionalities for cardiac and coronary CT angiography studies. The software accepts gated cardiac CT images, with optional ECG data, and generates automated and user-defined analysis outputs.

Automated outputs include cardiac chamber and aortic root segmentation, coronary artery centerlines, coronary artery labeling, and coronary lumen and wall segmentation. User-defined outputs include stenosis and plaque findings, cardiac function parameters, and CAD-RADS 2.0 reporting information.
Key features include standard cardiac CT viewing tools, image manipulation and measurement capabilities, automated segmentation with user review and editing, and semi-automatic coronary stenosis and plaque assessment. The device supports CAD-RADS 2.0 stenosis categorization and reporting based on user-confirmed findings.
Algorithms that are new or updated in the subject device include automated coronary centerline extraction (with an AI-based step), vessel labeling, and coronary lumen segmentation. All algorithm outputs are reviewable and editable by the user, and the device does not perform autonomous clinical interpretation.

Indications for Use

The AV Cardiac CT applications are intended to assist the user in viewing, processing, analysis of CT datasets and in preparation of cardiac interventions.

The CT Coronary Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of coronary artery anatomy for patients with suspected or diagnosed cardiac disease including coronary artery disease.

The CT Functional Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of heart anatomy and function, for patients with suspected or diagnosed cardiac diseases.

Verification and Validation

Software verification and validation activities were performed to verify that the software meets the product requirements.

Verification

Verification was performed according to the verification plan. Product requirement specifications were tested and found meeting the requirements.

Validation

Validation was performed according to the validation plan. User requirement specifications were tested and found meeting the requirements. The validation results provide evidence that the product meets its intended use and user requirements.

Performance Data

Performance testing was conducted to evaluate the automated coronary artery centerline extraction (with AI-based step), major vessel labeling, and the coronary artery lumen segmentation algorithms. The testing datasets were composed to represent the targeted US patient population in terms of key demographics, clinical and technical characteristics.

1. Coronary Artery Centerline Extraction

To validate the performance of centerline extraction, ECG-gated Coronary CT Angiography (CCTA) scans from 80 patients were collected.

The coronary artery centerlines automatically generated by the algorithm in the subject device were compared with a reference standard in terms of Overlap (OV), OV for the clinically relevant part (OT), and average distance (AvgDist).

- Testing Data, Demographics, & Independence from Training Data

The demographic information of the 80 patients included for performance testing is as follows:

Demographics	Number of patients (percentage)
Geographics	North America: 51 (63.75%) Europe: 19 (38%) Asia: 10 (12.5%)
Sex	Male: 47 (58.75%) Female: 33 (41.25%)
Age (years)	21-40: 3 (3.75%) 41-50: 4 (5%) 51-60: 11 (13.75%) 61-70: 21 (26.25%) 71-80: 31 (38.75%) >80: 4 (5%) Not available: 6 (7.5%)

The performance testing data were collected retrospectively from eight clinical sites in the US, three hospitals in Europe, and two hospitals in Asia. The algorithm model was developed with training data collected from completely distinct clinical sites, ensuring independence between training and testing data. All testing data were obtained from patients with suspected or confirmed coronary artery disease, encompassing various stenosis degrees, calcification scores, and plaque presence. The composed testing data were considered representative of the intended patient population in the US.

- Reference Standard (i.e., Truthing Process)

For each coronary artery in CCTA images as per the SCCT coronary segment model, one US-board certified radiologist and two US-board certified cardiologists (i.e., 3 observers) independently annotated the centerline in a fully manual manner. The annotation order of the cases was randomized for each observer to reduce bias. After quality control, per coronary artery, the three observer-annotated centerlines were averaged as the reference standard.

- Performance & Acceptance Criteria

For the performance metrics (OV, OT, and AvgDist), the acceptance criteria and performance statistics described as mean and confidence interval (CI) are:

Metrics	Acceptance criteria	Mean (98.3% CI)
OV	>0.80	0.93 (0.90 – 0.95)
OT	>0.85	0.94 (0.91 – 0.95)
AvgDist (mm)	<0.55 mm	0.35 (0.34 – 0.37) mm

- Clinical Subgroups & Confounders

The performance of centerline extraction was evaluated internally using independent testing CCTA data acquired with multi-vendor scanners (GE Healthcare, Siemens, Philips, Toshiba/Canon). The performance metrics (OV, OT, and AvgDist) were analyzed across subgroups (defined by sex, age group, data source, dominance, CT type, reconstruction method, CT manufacturer, regional image artifact, stenosis severity, plaque presence, and calcification scores). Anomalous major vessel origins, continuous calcification, heavily opacified coronary veins, and severe motion artifacts may deteriorate the accuracy of the centerline extraction.

2. Major Vessel Labeling

To validate the labeling accuracy of major coronary arteries, the algorithm-generated labels were compared with reference labels established by consensus among three US-board certified observers. The names of major coronary arteries

can be correctly labelled with an overall sensitivity of 0.91 and precision of 0.97. The lower bounds of 95% CI of both sensitivity and precision were >0.85.

3. Lumen Segmentation

To validate the performance of coronary artery lumen segmentation, ECG-gated CCA scans from 80 patients were collected.

The coronary artery lumen automatically generated by the algorithm in the subject device was compared with a reference standard in terms of Dice similarity coefficient (DSC), mean surface distance (MSD), and Hausdorff distance (HD).

- Testing Data, Demographics, & Independence from Training Data

The demographic information of the 80 patients included for performance testing is as follows:

Demographics	Number of patients (percentage)
Geographics	North America: 68 (85%) Europe: 12 (15%)
Sex	Male: 52 (65%) Female: 26 (32.5%) N/A: 2 (2.5%)
Age (years)	21-40: 1 (1.25%) 41-50: 5 (6.25%) 51-60: 8 (10%) 61-70: 24 (30%) 71-80: 32 (40%) >80: 4 (5%) Not available: 6 (7.5%)

The testing data for the primary study were retrospectively collected from 7 clinical sites in the US and 3 hospitals in Europe. The algorithm model was developed with data collected from completely distinct clinical sites, ensuring independence between training and testing data. All testing data were obtained from patients with suspected or confirmed coronary artery disease, encompassing various stenosis degrees, calcification scores, and plaque presence. The composed testing data were considered representative of the intended patient population in the US.

- Reference Standard (i.e., Truthing Process)

For each coronary artery in the CCTA, 3 US-board certified observers (radiologists and cardiologists) independently annotated the lumen contours. The order of the cases was randomized for each observer to reduce bias. After quality control, for each coronary artery, the three observer-annotated lumen contours were averaged as the reference standard.

- Performance & Acceptance Criteria

For the performance metrics (DSC, MSD, HD), the acceptance criteria and performance statistics described as mean and confidence interval (CI) are:

Metrics	Acceptance criteria	Median (98.3% CI)
DSC	DSC>0.7	0.83 (0.81, 0.84)
MSD [mm]	MSD<0.65mm	0.23 (0.22, 0.26) mm
HD [mm]	HD<4.0mm	1.45 (1.39, 1.55) mm

- Clinical Subgroups & Confounders

The performance of lumen segmentation was evaluated internally using independent testing CCTA data acquired with multi-vendor scanners (GE

Healthcare, Siemens, Philips, Toshiba/Canon). The performance metrics (DSC, MSD, and HD) were analyzed across subgroups (defined by sex, age group, data source, dominance, vessel, CT type, reconstruction kernel, CT manufacturer, vessel-level artifact, stenosis severity, vessel narrowing, plaque presence, calcification scores, and luminal opacification level). Image artifacts (e.g. motion artifacts) and insufficient luminal opacification (<250HU) may deteriorate the accuracy of the lumen segmentation.

Substantial Equivalence

AV Cardiac CT is as safe and effective as its predicate device. Both devices have the same intended use and similar indications for use, technological characteristics, and principles of operation. The minor technological differences between AV Cardiac CT and its predicate device raise no new issues of safety or effectiveness.

Performance data demonstrate that Philips Medical Systems' AV Cardiac CT is safe and effective. Thus, AV Cardiac CT is substantially equivalent to Philips Medical Systems' Spectral CT Applications, specifically the Spectral enhanced Comprehensive Cardiac Analysis (sCCA) application. Table 1 below summarizes the substantive feature/technological similarities and differences between the subject and predicate devices.

Table 1. Substantial Equivalence

Comparison Feature	**Subject Device** **Philips Medical Systems' AV Cardiac CT**	**Predicate Device** **Philips Medical Systems' Spectral CT Applications (K150665)**	**Reference device GE Medical Systems' CardIQ Suite**	**Comparison between the subject and predicate (identical/ different)**
Device Class	Class II	Class II	Class II	Identical
Classification Panel	Radiology	Radiology	Radiology	Identical
Product Code	JAK, QIH (subsequent)	JAK, LLZ (subsequent)	JAK, LLZ (subsequent)	Similar
Regulation Description	Computed tomography x-ray system (primary). Medical image management and processing system (subsequent).	Computed tomography x-ray system (primary) Medical image management and processing system (subsequent)	Computed tomography x-ray system (primary) Medical image management and processing system (subsequent)	Identical
Regulation Number	21 CFR 892.1750 21 CFR 892.2050	21 CFR 892.1750 21 CFR 892.2050	21 CFR 892.1750 21 CFR 892.2050	Identical

Comparison Feature	Subject Device Philips Medical Systems' AV Cardiac CT	Predicate Device Philips Medical Systems' Spectral CT Applications (K150665)	Reference device GE Medical Systems' CardIQ Suite	Comparison between the subject and predicate (identical/ different)
Indications for Use	The AV Cardiac CT applications are intended to assist the user in viewing, processing, analysis of CT datasets and in preparation of cardiac interventions. The CT Coronary Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of coronary artery anatomy for patients with suspected or diagnosed cardiac disease including coronary artery disease. The CT Functional Analysis application is indicated to assist radiologists, cardiologists, and 3D technologists in the analysis of heart anatomy and function, for patients with suspected or diagnosed cardiac diseases.	The Philips Spectral CT Applications support viewing and analysis of images at energies selected from the available spectrum in order to provide information about the chemical composition of the body materials and/or contrast agents. The Spectral CT Applications provide 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. The Spectral enhanced Advanced Vessel Analysis (sAVA) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of contrast-enhanced vessels. The Spectral enhanced Comprehensive Cardiac Analysis (sCCA) application is intended	CardIQ Suite is a non-invasive software application designed to provide an optimized application to analyze cardiovascular anatomy and pathology based on 2D or 3D CT cardiac non contrast and angiography DICOM data from acquisitions of the heart. It provides capabilities for the visualization and measurement of vessels and visualization of chamber mobility. CardIQ Suite also aids in diagnosis and determination of treatment paths for cardiovascular diseases to include, coronary artery disease, functional parameters of the heart, heart structures and follow-up for stent placement, bypasses and plaque imaging. CardIQ Suite provides calcium scoring, a non-invasive software application, that can be used with	Different

Comparison Feature	Subject Device Philips Medical Systems' AV Cardiac CT	Predicate Device Philips Medical Systems' Spectral CT Applications (K150665)	Reference device GE Medical Systems' CardIQ Suite	Comparison between the subject and predicate (identical/ different)
		to assist clinicians in viewing and evaluating cardiovascular CT images. The Spectral enhanced Tumor Tracking (sTT) application is intended to assist clinicians in viewing and evaluating CT images, for the inspection of tumors.	non-contrasted cardiac images to evaluate calcified plaques in the coronary arteries, heart valves and great vessels such as the aorta. Calcium Scoring may be used to monitor the progression/regression of calcium in coronary arteries overtime, which may aid in the prognosis of cardiac disease.	
Clinical Characteristics				
Intended body part	Cardiovascular anatomy (heart and coronary vessels)	Cardiovascular anatomy (heart and coronary vessels)	Cardiovascular anatomy (heart and coronary vessels)	Identical
Type of scans	CT scans (conventional and spectral)	CT scans (conventional and spectral)	CT scans	Identical
Technological features				
DICOM	Yes	Yes	Yes	Identical
Coronary artery segmentation including automated centerline extraction, vessel labelling, lumen, and	Yes Includes new algorithm for centerline extraction (CNN - deep learning component included), updated vessel labelling algorithm (model based) and new lumen segmentation algorithm (KNN model). In	Yes Includes legacy algorithms (non-AI) for centerline extraction, vessel labelling, lumen and wall segmentation.	Yes	Different

Comparison Feature	Subject Device Philips Medical Systems' AV Cardiac CT	Predicate Device Philips Medical Systems' Spectral CT Applications (K150665)	Reference device GE Medical Systems' CardIQ Suite	Comparison between the subject and predicate (identical/ different)
wall segmentation	addition, includes unchanged wall segmentation algorithm (non-AI)			
CAD-RADS 2.0 stenosis categorization and structured reporting	Yes categorization according to CAD-RADS 2.0 standard is new.	Yes	No	Different