Philips Medical Systems Nederland B.V.
Arbel Shezaf
Regulatory Affairs Manager
Veenpluis 6
Best, 5684 PC
Netherlands

January 22, 2026

Re: K253735
Trade/Device Name: AV Vascular
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: November 24, 2025
Received: November 24, 2025

Dear Arbel Shezaf:

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.

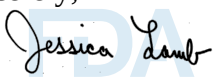
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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,



Jessica Lamb, Ph.D.
Imaging Software Team
Assistant Director
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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.	K253735

Please provide the device trade name(s).

AV Vascular

Please provide your Indications for Use below.

AV Vascular is indicated to assist users in the visualization, assessment and quantification of vascular anatomy on CTA and/or MRA datasets, in order to assess patients with suspected or diagnosed vascular pathology and to assist with pre-procedural planning of endovascular interventions.

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 Vascular

Company's Name and Address	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
Contact Person	Arbel Shezaf Regulatory Affairs Manager MATAM building 34, Haifa, 3100202, Israel +972544487597 arbel.shezaf@philips.com
Date	January 22, 2026
Device Trade name	AV Vascular
Classification Name	Automated radiological image processing software
Primary Product Code	QIH
Secondary Product Code	LLZ
Classification	21 CFR 892.2050
Primary Predicate Device	Pie Medical Imaging's 3mensio Structural Heart / 3mensio Vascular (K153736)
Secondary Predicate Device	Philips Medical Systems' The Multimodality Advanced Vessel Analysis (MM AVA) application (K203216)
Reference Device	Philips Medical Systems' Spectral CT Applications (K150665)
Device Description	AV Vascular is a post-processing software application intended for visualization, assessment, and quantification of vessels in computed tomography angiography (CTA) and magnetic resonance angiography (MRA) data with a unified workflow for both modalities. AV Vascular includes the following functions: • Advanced visualization: the application provides all relevant views and interactions for CTA and MRA image review: 2D slides, MIP, MPR, curved MPR (cMPR), stretched MPR (sMPR), path-aligned views (cross-sectional and longitudinal MPRs), 3D volume rendering (VR). • Vessel segmentation: automatic bone removal and vessel segmentation for head/neck and body CTA data, automatic vessel centerline, lumen and outer wall extraction and labeling for the main branches of the vascular anatomy in head/neck and body CTA data, semi-automatic and manual creation of vessel centerline and lumen for CTA and MRA data, interactive two-point vessel centerline extraction and single-point centerline extension. • Vessel inspection: enable inspection of an entire vessel using the cMPR or sMPR views as well as inspection of a vessel locally using vessel-aligned views (cross-sectional and longitudinal MPRs) by selecting a position along a vessel of interest. • Measurements: ability to create and save measurements of vessel and lumen inner and outer diameters and area, as well as vessel length and angle measurements. • Measurements and tools that specifically support pre-procedural planning: manual and automatic ring marker placement for specific anatomical locations, length measurements of the longest and shortest curve along the aortic lumen contour, angle measurements of aortic branches in clock position style, saving viewing angles in C-arm notation, and configurable templated

measurements.
- Saving and export: saving and export of batch series and customizable reports.

Indications for Use

AV Vascular is indicated to assist users in the visualization, assessment and quantification of vascular anatomy on CTA and/or MRA datasets, in order to assess patients with suspected or diagnosed vascular pathology and to assist with pre-procedural planning of endovascular interventions.

Verification and Validation

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

Verification and Validation

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

Validation

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

Performance Data

Performance testing was conducted for subclavian artery extraction on body cases (model-based algorithm), aorto-iliac wall segmentation (AI-based algorithm) and ring marker placement (model-based algorithm). The datasets represent the targeted US patient population in terms of key demographics, clinical and technical characteristics.

Subclavian Artery Centerline Extraction

CT angiography scans of the body were collected for testing. The automatically extracted subclavian artery centerlines were compared with a reference standard.

Ring Marker Placement

CT angiography scans of the body were collected for testing, with the majority coming from patients with aortic or iliac aneurysms. Automatically placed ring markers at the ostia of the renal and superior mesenteric arteries were evaluated by expert vascular interventionalists for their clinical acceptability without any adjustment.

Aorto-iliac Outer Wall Segmentation

To validate the performance of the aorto-iliac wall segmentation, body CT angiography scans were collected from 80 patients.

The aorto-iliac outer wall contour automatically generated by the AI-based 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). The measurement accuracy (minimum and maximum diameter, D_{min} and D_{max}) was also evaluated.

- Testing Data, Demographics, & Independence from Training Data
  The demographic information of the 80 patients included for performance testing is:

Demographics	Number of patients (percentage)
Geographics	North America: 58 (72.5%) Europe: 3 (3.75%) Asia: 19 (23.75%) None of these testing data were from the same clinical sites which provided the training data.
Sex	Male: 59 (73.75%) Female: 21 (26.25%)
Age (years)	21-50: 2 (2.50%) 51-70: 31 (38.75%)

	>71:	45 (56.25%)
	Not available:	2 (2.5%)

The performance testing data were collected retrospectively from 7 clinical sites in the US, 3 European hospitals, and one hospital in Asia. All performance testing datasets were acquired from clinical sites distinct from those which provided the algorithm training data, and the algorithm developers had no access to the testing data, ensuring complete independence between training and testing data. At least 80% of the included patients had thoracic and/or abdominal aortic diseases and/or iliac artery diseases (e.g., thoracic/abdominal aortic aneurysm, ectasia, dissection, and stenosis). At least 20% of patients had been treated with stents. The composed testing data were considered representative of the intended patient population in the US.

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

  For each of the CT angiographic images, three US-board certified radiologists (i.e., truthers) independently performed manual contouring of the outer wall along the aorta and iliac arteries on cross-sectional planes. The order of the cases was randomized for each truther to reduce bias. After quality control, these three aortic and iliac arterial outer wall contours were averaged as the reference standard contour.

- Performance & Acceptance Criteria

  For primary performance metrics (2D and 3D DSC, MSD, and HD) the performance statistics and acceptance criteria are:

Metrics		**Acceptance criteria**	**Mean (98.75% confidence intervals)**
DSC	3D	DSC > 0.9	0.96 (0.96, 0.97)
	2D	DSC > 0.9	0.96 (0.95, 0.96)
MSD [mm]		MSD < 1.0 mm	0.57 (0.485, 0.68)
HD [mm]		HD < 3.0 mm	1.68 (1.23, 2.08)

For secondary performance metrics (D_{min} and D_{max}), the performance statistics and acceptance criteria are:

Metrics	**Acceptance criteria**	**Proportion (95% confidence intervals)**
ΔD_{min}	>95% $\lvert\Delta D_{min}\rvert$<5 mm	98.8% (98.3-99.2%)
ΔD_{max}	>95% $\lvert\Delta D_{max}\rvert$<5 mm	98.5% (97.9-98.9%)

- Clinical Subgroups & Confounders

  The performance of automatic aorto-iliac outer wall segmentation was evaluated internally using independent testing CT angiographic data acquired with multi-vendor scanners (GE Healthcare, Siemens, Philips, Toshiba/Canon) from patients of which at least 80% had aortic and/or iliac artery aneurysm, dissection, stents, calcification, stenosis, and/or plaque. Primary performance metrics (DSC, MSD, and HD) were analyzed across subgroups (defined by sex, age group, data source, vessel, pathology, reconstruction method, slice thickness, and manufacturer). The algorithm's performance was consistent across multiple subgroups and comparable to the inter-truther variability. The outer wall segmentation accuracy, however, might be reduced in cases of giant aneurysms (diameter > 10 cm), which is rare in the intended patient population.

Therefore, the performance of all three algorithms is state of the art and on par with the expectation.

Substantial Equivalence

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

Performance data demonstrate that Philips Medical Systems' AV Vascular is safe and effective. Thus, AV Vascular is substantially equivalent to Pie Medical Imaging's 3mensio. 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 Vascular**	**Predicate Device** **Pie Medical Imaging's 3mensio Structural Heart / 3mensio Vascular (K153736)**	**Secondary Predicate Device** **Philips Medical Systems' Multimodality Advanced Vessel Analysis (MM AVA) application (K203216)**	**Reference Device** **Philips Medical Systems' Spectral CT Applications (K150665)**	**Comparison between the subject and predicate devices (identical/ different)**
Device Class	Class II	Class II	Class II	Class II	Identical
Classification Panel	Radiology	Radiology	Radiology	Radiology	Identical
Product Code	QIH, LLZ	LLZ	JAK	JAK, LLZ	Similar to primary predicate device
Regulation Description	Medical image management and processing system	Medical image management and processing system	Computed tomography x-ray system	Computed tomography x-ray system Medical image management and processing system	Identical to primary predicate device
Regulation Number	892.2050	892.2050	892.1750	892.1750 892.2050	Identical to primary predicate device
Indications for Use	AV Vascular is indicated to assist users in the visualization, assessment and quantification of vascular anatomy	3mensio Workstation is a standalone software for medical image analysis intended for advanced	The Multimodality Advanced Vessel Analysis (MM AVA) application is intended for visualization, assessment and	The Philips Spectral CT Applications support viewing and analysis of images at energies selected	Different

Comparison Feature	Subject Device Philips Medical Systems' AV Vascular	Predicate Device Pie Medical Imaging's 3mensio Structural Heart / 3mensio Vascular (K153736)	Secondary Predicate Device Philips Medical Systems' Multimodality Advanced Vessel Analysis (MM AVA) application (K203216)	Reference Device Philips Medical Systems' Spectral CT Applications (K150665)	Comparison between the subject and predicate devices (identical/ different)
	on CTA and/or MRA datasets, in order to assess patients with suspected or diagnosed vascular pathology and to assist with pre-procedural planning for endovascular interventions.	visualization and quantitative analysis for diagnostic and/or for assistance during treatment in the field of cardiology or radiology by means of enabling visualization and measurement of structures of the heart and vessels for: • Pre-operational planning and sizing for cardiovascular interventions and surgery • Postoperative evaluation • Support of clinical diagnosis by quantifying dimensions in coronary arteries • Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the coronary arteries To facilitate the above, the 3mensio Workstation provides general functionality such as:	quantification of vascular datasets.	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.	

Comparison Feature	Subject Device Philips Medical Systems' AV Vascular	Predicate Device Pie Medical Imaging's 3mensio Structural Heart / 3mensio Vascular (K153736)	Secondary Predicate Device Philips Medical Systems' Multimodality Advanced Vessel Analysis (MM AVA) application (K203216)	Reference Device Philips Medical Systems' Spectral CT Applications (K150665)	Comparison between the subject and predicate devices (identical/ different)
		• Segmentation of cardiovascular structures • Automatic and manual centerline detection • Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR, Curved MPR, Stretched CMRP, Slabbing, MIP, AIP, MinIP • Measurement and annotation tools Reporting tools		The Spectral enhanced Comprehensive Cardiac Analysis (sCCA) application is intended 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.	
Clinical Characteristics					
Intended body part	Head and neck, body, peripherals	Heart and vessels	Head and neck, body, peripherals	Head and neck, body, peripherals	Identical to secondary predicate device
Type of scans	CTA and MRA	CT Angiography	CTA and MRA	CT Angiography	Identical to secondary predicate device
Technological features					
Spectral capabilities	Yes	No	No	Yes	Identical to reference device
Subclavian Artery	Automatic vessel centerline extraction of the head, neck and	Automatic vessel centerline extraction	Automatic vessel centerline	Automatic vessel centerline	Different

Comparison Feature	Subject Device Philips Medical Systems' AV Vascular	Predicate Device Pie Medical Imaging's 3mensio Structural Heart / 3mensio Vascular (K153736)	Secondary Predicate Device Philips Medical Systems' Multimodality Advanced Vessel Analysis (MM AVA) application (K203216)	Reference Device Philips Medical Systems' Spectral CT Applications (K150665)	Comparison between the subject and predicate devices (identical/ different)
Centerline Extraction	body including shoulder region		extraction of the head and neck	extraction of the head and neck	
Aorto-iliac Outer Wall Segmentation	Automatic non-AI based vessel contouring of major vessels. Automatic AI-based vessel contouring specifically for the aorta and common and external iliac arteries.	No	Automatic non-AI based vessel contouring of major vessels, including the aorta and common and external iliac arteries.	Automatic non-AI based vessel contouring of major vessels, including the aorta and common and external iliac arteries.	Different
Review Marker tool	Review Marker tool including manual ring markers, and non-AI based automatic ring markers for the ostia of the SMA, LRA and RRA	Review Marker tool including manual ring markers	Review Marker tool	Review Marker tool	Different