November 25, 2020

Philips Medical Systems Nederland B.V.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

Re: K203216
Trade/Device Name: The Multimodality Advanced Vessel Analysis (MM AVA) application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: October 28, 2020
Received: November 2, 2020

Dear Prithul Bom:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K203216

Device Name
The Multimodality Advanced Vessel Analysis (MM AVA) application

Indications for Use *(Describe)*
The Multimodality Advanced Vessels Analysis (MM AVA) application is intended for visualization, assessment and quantification of vascular datasets.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

The Multimodality Advanced Vessel Analysis (MM AVA) Application

**Date Prepared:** October 6, 2020

## I. Submitter's name and address

**Manufacturer:** Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

**Primary Contact Person:** Vered Nitzan
Regulatory Affairs Lead
Phone: +972 54-9797047
E-mail: vered.nitzan@Philips.com

## II. Device information

| | | |
|---|---|---|
| **Device:** | Trade Name: | The Multimodality Advanced Vessel Analysis (MM AVA) application |
| | Classification Name: | Computed tomography x-ray system |
| | Classification Regulation: | 21 CFR 892.1750 |
| | Classification Panel: | Radiology |
| | Device Class: | II |
| | Primary Product Code: | JAK |

## III. Device Description

Philips Medical Systems' ***Multimodality Advanced Vessels Analysis (MM AVA)*** application is intended for visualization, assessment, and quantification of vessels in CTA and MRA data with a unified workflow for both modalities. For CTA data, it provides both automatic and manual bone

removal and vessels segmentation including extraction of vessel centerlines, lumen contours and vessel contours. For both modalities, it provides tools for extracting and editing centerlines.

MM AVA offers inspection views for selected vessels centerlines and local analysis. It allows creating, capturing, and reviewing of basic user selected endovascular measurements (and calculations when applicable), as well as predefined measurements sets and measurements correlations.

The physician retains the ultimate responsibility for making the final diagnosis.

Philips Medical Systems' MM AVA is launched from Philips Medical Systems' IntelliSpace Portal (ISP) Platform (K162025).

**Key Features:**

1. Provides automatic bone removal for CTA data
2. Provides automatic vessel centerline extraction and labeling for the main vessels (CTA data)
3. Provides a set of centerline creation and editing tools (manual and semi-automatic)
4. Provides dedicated views for vessels review: Curved MPRS, Straighten MPR, Cross-sectional and Longitudinal MPR
5. Provides 3D Volume rendering capabilities for CTA and MRA, including different volumetric presentation options such as Volume rendering, MIP (Maximum Intensity Projection) etc.
6. Allows measurements along a vessel centerline, based on a user selected location/s – such as Max Diameter, Min Diameter and Area
7. Allows the calculation of measurements such as: Length, Angle, Tortuosity, Stenosis, Aneurysm etc. based on user selected locations and their intra-correlations.
8. Allows navigation and local inspection of images, including capturing measurements such as diameters (Quick Inspection)
9. Allows Batch (series of images processed by user) generation for any of the selected user views.

## IV. Intended Use and Indications for Use:

The Multimodality Advanced Vessels Analysis (MM AVA) application is intended for visualization, assessment, and quantification of vascular datasets.

## V. Predicate Devices:

The following table shows the predicate devices of the proposed Philips Medical Systems Multimodality Advanced Vessels Analysis (MM AVA) application:

| | Device Name | Manufacturer | 510k No |
|---|---|---|---|
| Primary Predicate | Brilliance Volume | Philips Medical Systems (Cleveland), Inc. | K060937 |
| Secondary Predicate | syngo.CT Vascular Analysis | Siemens Medical Solutions, Inc. | K112020 |
| Secondary Predicate | syngo.MR Vascular | Siemens Medical Solutions, Inc. | K130749 |

The proposed Philips Medical Systems Multimodality Advanced Vessels Analysis (MM AVA) application and its predicate devices, Brilliance Volume (K060937), syngo.CT Vascular Analysis (K112020) and syngo.MR Vascular (K130749) are equivalent regarding their intended uses, clinical indications, principle of operation and fundamental technology.

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## VI. Substantial Equivalence to Predicate Devices:

| Feature | The proposed device: MM AVA Application | Primary Predicate: Brilliance Volume (K060937) | Secondary Predicate: Siemens syngo.CT Vascular Analysis (K112020) | Secondary Predicate: Siemens syngo.MR Vascular (K130749) |
|---|---|---|---|---|
| **Device Classification Name** | System, X-Ray, Tomography, Computed | System, X-Ray, Tomography, Computed | System, X-Ray, Tomography, Computed | System, Image Processing, Radiological |
| **Device Class** | Class II | Class II | Class II | Class II |
| **Classification Panel** | Radiology | Radiology | Radiology | Radiology |
| **Product Code** | JAK | JAK | JAK | LLZ, LNH |
| **Regulation Description** | Computed tomography x-ray system | Computed tomography x-ray system | Computed tomography x-ray system | Picture Archiving and Communication System (PACS) |
| **Regulation Number** | 21 CFR 892.1750 | 21 CFR 892.1750 | 21 CFR 892.1750 | 21 CFR 892.2050 |
| **Indication for Use** | The Multimodality Advanced Vessels Analysis (MM AVA) application is | The "Brilliance Volume" is a Computed Tomography X-Ray System intended to | syngo CT Vascular Analysis is an image analysis software package | The software comprising the syngo.MR post-processing applications are |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| | intended for visualization, assessment and quantification of vascular datasets. | produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories. | for evaluating enhanced CT images. Combining digital image processing and visualization tools (multiplanar reconstruction (MPR) thin/thick, maximum intensity projection (MIP) thin/thick, inverted MIP thin/thick, volume rendering technique (VRT), curved planar reformation (CPR), processing tools (bone removal (based both on single energy and Dual Energy), table removal) and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics and | post-processing software / applications to be used for viewing and evaluating the designated images provided by a magnetic resonance diagnostic device.<br><br>syngo.MR Vascular is a syngo based post-processing software for viewing, manipulating, and evaluating MR vascular images. |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| | | | key images), the software package is designed to support the physician in confirming the presence or absence of physician-identified lesions in blood vessels and evaluation, documentation and follow-up of any such lesion. These visualization/processing/evaluation tools allow for characterization of vascular lesions and lesion size over time, helping the physician to assess the changes in their growth. It is also designed to help the physician classify conspicuous regions of tissue. | |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Intended body part** | Head and neck, body, peripherals | Head and neck, body, peripherals | Head and neck, body, peripherals | Head and neck, body, peripherals |
| **Type of scans** | CT Angiography and MR Angiography | CT Angiography | CT Angiography | MR Angiography |
| **Automatic bone removal for CTA data** | Yes | Yes | Yes<br>(Including Dual Energy) | NA |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Semi-automatic bone removal for CTA data** | Yes | Yes | Yes | No |
| **Bone Removal Edit for CTA data**<br>Manual interactions for correction of bone removal results. | Yes | Yes | Yes | NA |
| **Automatic vessel centerline extraction** | Yes (CT only) | Yes | Yes | No |
| **Automatic vessel labeling** | Yes (CT only) | Yes | Yes | No |
| **Manual Vessel Tracking**<br>Manual drawing and editing of vascular paths for curved MPR | Yes (manual and semi-automatic) | Yes | Yes | Yes |

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| Feature | The proposed device: MM AVA Application | Primary Predicate: Brilliance Volume (K060937) | Secondary Predicate: Siemens syngo.CT Vascular Analysis (K112020) | Secondary Predicate: Siemens syngo.MR Vascular (K130749) |
|---|---|---|---|---|
| visualization | | | | |
| **Vessel Tracking**<br>Tools for semi-automatic tracking and editing of vascular structures. | Yes | Yes | Yes | Yes |
| **Vessel centerline and lumen contours extraction** | Yes | Yes | Yes | Yes |
| **(Semi) automatic segmentation of vessel anatomy** | Yes | Yes | Yes | Yes |
| **Curved MPR (CPR) and Cross Section MPR**<br>Visualization of vessels in curved MPR with corresponding cross-sectional Images. | Yes | Yes | Yes | Yes |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Curved reformat vessel views** | Yes | Yes | Yes | Yes |
| **Vessel aligned MPR views** (Straighten MPR) | Yes | Yes | Yes | Yes |
| **3D volumetric vessel views** | Yes | Yes | Yes | Yes |
| **Diameter measurement** | Yes | Yes | Yes | Yes |
| **Stenosis Measurement**<br>Stenosis values based on lumen contouring. | Yes | Yes | Yes | Yes |
| **Aneurysm measurement** | Yes | Yes | Not specified | Not specified |
| **3D vascular measurements (diameter, stenosis, aneurysm)** | Yes | Yes | Yes | Yes |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Measurements editing**<br>Functionality for editing values of clinical findings such as location, pathology, etc. | Yes | Yes | Yes | Yes |
| **Lumen evaluation**<br>Delineation of vessel contours for vascular analysis | Yes | Yes | Yes | Yes |
| **Navigate Along Vessel**<br>Semi-automatic alignment of MPR views to local vascular anatomy with interactive navigation along vessel course. | Yes | Yes | Yes | Yes |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Review Marker**<br>Functionality for setting location of a clinical finding on any view. | Yes | Yes | Yes | Yes |
| **Curved and Cross-Sectional Ranges**<br>Creation of MPR series around and along vessels path. | Yes | Yes | Yes | Yes |
| **Basic Reading Functionality**<br>Conventional navigation on 2D and 3D views, change of layouts, adapt window values. | Yes | Yes | Yes | Yes |
| **Bone Opacity for CTA data** | Yes | Yes | Yes | NA |

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| Feature | The proposed device:<br>MM AVA Application | Primary Predicate:<br>Brilliance Volume<br>(K060937) | Secondary Predicate:<br>Siemens syngo.CT Vascular Analysis<br>(K112020) | Secondary Predicate:<br>Siemens syngo.MR Vascular<br>(K130749) |
|---|---|---|---|---|
| **Table (couch) Removal**<br>Segmentation of patient table for clear VRT visualization of anatomy. | Yes | Yes | Yes | NA |
| **Angio View**<br>Inverted MIP visualization of vessels filled with contrast agent. | Yes | Yes | Yes | Yes |
| **Calcification Removal for CTA data**<br>Masking of high intensity structures along vessels for true lumen visualization. | Yes | Yes | Yes<br>(also for dual energy) | NA |
| **DICOM compatible** | Yes | Yes | Yes | Yes |

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The proposed Philips Medical Systems Multimodality Advanced Vessels Analysis (MM AVA) application and its predicate devices, Brilliance Volume (K060937), syngo.CT Vascular Analysis (K112020) and syngo.MR Vascular (K130749) are substantially equivalent in regard to their intended use, clinical indications, principle of operation and fundamental technology.

In conclusion, Philips believes that the Multimodality Advanced Vessels Analysis (MM AVA) application does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate devices, Brilliance Volume (K060937), syngo.CT Vascular Analysis (K112020) and syngo.MR Vascular (K130749).

## VII. Nonclinical Tests performed:

Non-clinical performance tests has been performed on Multimodality Advanced Vessels Analysis (MM AVA) application and demonstrates compliance with the following International and FDA-recognized consensus standards:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- NEMA PS 3.1-3.21 - Digital Imaging and Communications in Medicine (DICOM) Standard
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

Philips Medical Systems ***Multimodality Advanced Vessels Analysis (MM AVA) application*** was tested in accordance with Philips verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics, requirement specifications and the risk management results.

The test results in this 510(k) premarket notification demonstrate that Multimodality Advanced Vessels Analysis (MM AVA) application:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance documents, and
- Meets the acceptance criteria and is adequate for its intended use and specifications.

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## VIII. Overall Conclusion:

The ***Multimodality Advanced Vessels Analysis (MM AVA) application*** is substantially equivalent to the identified predicate devices, Brilliance Volume (K060937), syngo.CT Vascular Analysis (K112020) and syngo.MR Vascular (K130749) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation tests demonstrate the safety and efficacy of the device to meet its intended use and specifications.

Philips Medical believes that the proposed device**, *Multimodality Advanced Vessels Analysis (MM AVA) application***, is substantially equivalent to its identified predicate devices and is as safe and effective as its predicate devices without raising any new safety and/or effectiveness concerns.