March 30, 2026

ViTAA Medical Solutions, Inc.
% Kyle O'Sullivan
Associate, Regulatory Affairs
MCRA an IQVIA Business
803 7th St. NW
Washington, District of Columbia 20001

Re: K254207
Trade/Device Name: AiORTA - Plan v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 4, 2026
Received: March 4, 2026

Dear Kyle O'Sullivan:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254207

Device Name
AiORTA - Plan v2.0

Indications for Use *(Describe)*
The AiORTA - Plan tool is an image analysis software tool for volumetric assessment, image analysis, geometric analysis, and pre-operative sizing and planning. It provides volumetric visualization and measurements based on 3D reconstruction computed from cardiovascular CTA scans. The software device is intended to provide adjunct information to a licensed healthcare practitioner (HCP) in addition to clinical data and other inputs, as a measurement tool used in assessment of aortic aneurysm, pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation in patients 22 years old and older.
The device is not intended to provide stand-alone diagnosis or suggest an immediate course of action in treatment or patient management

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

Basic Information

Manufacturer: ViTAA Medical Solutions, Inc.
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Preparation Date: March 25, 2026

Subject Device trade name: AiORTA – Plan v2.0

Medical Specialty: Radiology

Classification: 21 CFR 892.2050

Regulation Name: Medical Image Management and Processing System

Common Name: Automated Radiological Image Processing Software

Class: II

Product Code: QIH

Predicate Device Trade Name: AiORTA – Plan v1.1 (K250337)

Medical Specialty: Radiology

Classification: 21 CFR 892.2050

Regulation Name: Medical Image Management and Processing System

Common Name: Automated Radiological Image Processing Software

Class: II

Product Code: QIH

Indications for use

The AiORTA - Plan tool is an image analysis software tool for volumetric assessment, image analysis, geometric analysis, and pre-operative sizing and planning. It provides volumetric visualization and measurements based on 3D reconstruction computed from cardiovascular CTA scans. The software device is intended to provide adjunct information to a licensed healthcare practitioner (HCP) in addition to clinical data and other inputs, as a measurement tool used in assessment of aortic aneurysm, pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation in patients 22 years old and older.

The device is not intended to provide stand-alone diagnosis or suggest an immediate course of action in treatment or patient management

Device description

AiORTA - Plan v2.0 is a cloud-based software tool used to make and review geometric measurements of cardiovascular structures, specifically abdominal aortic aneurysms. The software uses CT scan data as input to make measurements from 2D and 3D mesh based images. Software outputs are intended to be used as a measurement tool used in assessment of aortic aneurysm, pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation.

The AiORTA - Plan v2.0 software consists of two components, the Analysis Pipeline and Web Application.

The Analysis Pipeline is the data processing engine that produces measurements of the abdominal aorta based on the input DICOM images. It consists of multiple automated modules that are used to preprocess the DICOM images, compute geometric parameters (e.g., centerlines, diameters, lengths, volumes), and upload the results to the Web App for clinician review. The end user (licensed healthcare practitioner) is ultimately responsible for the accuracy of the segmentations, the resulting measurements, and any clinical decisions based on these outputs.

The workflow of the Analysis Pipeline can be described in the following steps:

- Input: the Analysis Pipeline receives a CTA scan as input.
- Segmentation: an AI-powered auto-masking algorithm performs segmentation of the aortic lumen, wall, and key anatomical landmarks, including the superior mesenteric, celiac, and renal arteries, as well as the external iliac arteries and a large portion of the descending aorta.
- 3D conversion: the segmentations are converted into 3D mesh representations.
- Measurement computation: from the 3D representations, the aortic centerline and geometric measurements, such as diameters, lengths, and volumes, are computed.
- Follow-up study analysis: for patients with multiple studies, the system can detect and display changes in aortic geometry between studies.
- Report generation: a report is generated by the user in the web application containing key measurements and a 3D Anatomy Map providing multiple views of the abdominal aorta and its landmarks. A detailed breakdown is presented including targeting landing zones and critical regions of interest and C-ARM calculations for proximal neck and distal left and right common iliac arteries.

- Web application integration: the outputs, including the segmented CT masks, and 3D visualizations, are uploaded to the Web App for interactive review and analysis.

The Web Application (Web App) is the front end and user facing component of the system. It is a cloud-based user interface offered to the qualified clinician to first upload de-identified cardiovascular CTA scans in DICOM format, along with relevant demographic and medical information about the patient and current study. The uploaded data is processed asynchronously by the Analysis Pipeline. Once processing is complete, the Web App then enables clinicians to interactively review and analyze the resulting outputs.

Main features of the Web App include:

- Full suite of image analysis tools: Clinicians can review segmentations and make manual corrections of all measurements generated by the software by viewing the CT slices alongside the segmentation masks. Segmentations can be revised using tools such as a brush or pixel eraser, with adjustable brush size, to select or remove pixels as needed. When clinicians revise segmentations, they can request asynchronous re-analysis by the Analysis Pipeline, which generates updated measurements and a 3D Anatomy Map of the aorta based on the revised segmentations.
- 3D visualization: The aorta and key anatomical landmarks can be examined in full rotational views using the 3D Anatomy Map.

- Measurement tools: Clinicians can perform measurements directly on the 3D Anatomy Map of the abdominal aorta and have access to a variety of measurement tools, including:
- Centerline distance, which measures the distance (in mm) between two user-selected planes along the aortic centerline.
- Diameter range, which measures the minimum and maximum diameters (in mm) within the region of interest between two user-selected planes along the aortic centerline.
- Local diameter, which measures the diameter (in mm) at the user-selected plane along the aortic centerline.
- Volume, which measures the volume (in mL) between two user-selected planes along the aortic centerline.
- Calipers, which allow additional linear measurements (in mm) at user-selected points.

- Screenshots: Clinicians can capture images of the 3D visualizations of the aorta or the segmentations displayed on the CT slices.
- Longitudinal analysis: For patients with multiple studies, the Web App allows side-by-side review of studies. Clinicians have access to the same measurement and visualization tools available in single-study review, enabling comparison between studies.
- Reporting: Clinicians can generate and download reports containing all measurements in the application measurements and screenshots captured during review.

Substantial Equivalence Comparison

Device Characteristic	**Predicate Device: AiORTA Plan 1.1 (K250337)**	**Subject Device: AiORTA Plan 2.0 (K254207)**	**Comparison**
Manufacturer	ViTAA Medical, Inc.	ViTAA Medical, Inc.	Identical
Classification	21 CFR 892.2050	21 CFR 892.2050	Identical
Product code	QIH	QIH	Identical
Intended use statement	The AiORTA - Plan tool is an image analysis software tool for volumetric assessment.	The AiORTA - Plan tool is an image analysis software tool for volumetric assessment,	Addition of “patients 22 years old and older” added to

Device Characteristic	Predicate Device: AiORTA Plan 1.1 (K250337)	Subject Device: AiORTA Plan 2.0 (K254207)	Comparison
	It provides volumetric visualization and measurements based on 3D reconstruction computed from cardiovascular CTA scans. The software device is intended to provide adjunct information to a licensed healthcare practitioner (HCP) in addition to clinical data and other inputs, as a measurement tool used in assessment of aortic aneurysm, pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation. The device is not intended to provide stand-alone diagnosis or suggest an immediate course of action in treatment or patient management.	image analysis, geometric analysis, and pre-operative sizing and planning. It provides volumetric visualization and measurements based on 3D reconstruction computed from cardiovascular CTA scans. The software device is intended to provide adjunct information to a licensed healthcare practitioner (HCP) in addition to clinical data and other inputs, as a measurement tool used in assessment of aortic aneurysm, pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation in patients 22 years old and older. The device is not intended to provide stand-alone diagnosis or suggest an immediate course of action in treatment or patient management	intended use & indications for use statement per FDA recommendation.
Use Environment	Hospital	Hospital	Identical
Intended end-user	Healthcare Practitioner	Healthcare Practitioner	Identical
Anatomical scope	Abdominal aorta	Abdominal aorta + external iliac arteries	The region of interest has been expanded in v2.0

Device Characteristic	Predicate Device: AiORTA Plan 1.1 (K250337)	Subject Device: AiORTA Plan 2.0 (K254207)	Comparison
		and a larger portion of the descending aorta	to give clinicians better ability to assess access vessels and supra-renal considerations. This expansion of ROI does not introduce new questions of safety or effectiveness.
Image source	Cardiovascular CTA scans	Cardiovascular CTA scans	Identical
Operating system	Microsoft Windows	Microsoft Windows	Identical
System configuration	Web application	Web application	Identical
Analysis workflow	Semi-automatic analysis pipeline requiring input from ViTAA analysts. Analysis is completed within 30 minutes under normal conditions.	Fully automated analysis pipeline. Clinicians retain the ability to edit outputs.	A full suite of image analysis tools for manual correction by a clinician has been added. All corrections and edits are performed by the physician.
Vessel geometry measurement tools	Provides tools for measuring vessel geometry, including diameters, lengths, and volumes.	All relevant measurements are provided automatically, along with a detailed breakdown targeting landing zones and other critical regions of interest.	Additional tools are provided to guide the user, while users can still edit or override the automated outputs.
Segmentation	**Semi-automatic** segmentation using auto-masking algorithm with **manual revisions**	**Automated** segmentation using masking algorithm. The end-user (clinician) can	Users in v2.0 have the option of employing an automated

Device Characteristic	Predicate Device: AiORTA Plan 1.1 (K250337)	Subject Device: AiORTA Plan 2.0 (K254207)	Comparison
	performed by trained **ViTAA analysts.** End-users (clinicians) can view and edit the segmentations.	view and edit these segmentations using the included suite of editing tools.	algorithm instead of a ViTAA analyst for segmentation. Clinicians retain control over the end result.
Centerline detection	**Automatic** centerline detection within the analysis pipeline. User edits of the centerline are not supported.	**Automatic** centerline detection within the analysis pipeline. User edits of the centerline are not supported.	Identical
Study comparison	Allows users to visualize two studies side-by-side across two viewports, enabling a direct comparison of structures between the studies. Provides measurement capabilities in comparison mode, allowing users to quantify changes in vessel geometries between the two studies.	Allows users to visualize two studies side-by-side across two viewports, enabling a direct comparison of structures between the studies. Provides measurement capabilities in comparison mode, allowing users to quantify changes in vessel geometries between the two studies. Provides device suggestions to the user based on product tables provided by the institution, using clinically-validated measurements.	Version 2.0 contains the addition of device suggestions based on look-up tables provided by the institution. This additional helpful information does not raise new questions of safety or effectiveness.
Change in geometric analysis	Reports automated measurements describing changes between two studies within the default volume of interest, including:	All previous calculations with the addition of C-ARM calculations for proximal neck and distal left and right common iliac arteries.	Additional calculations in the v2.0 device are included to accommodate the expanded ROI.

Device Characteristic	Predicate Device: AiORTA Plan 1.1 (K250337)	Subject Device: AiORTA Plan 2.0 (K254207)	Comparison
	• Change in Maximum Lumen Diameter • Change in Maximum Aortic Diameter • Change in Lumen Volume • Change in Aortic Volume		
Storage of results	• Report in PDF format • Viewports: Session state	• Report in PDF format • Viewports: Session state	Identical
VIEWPORT CONTROLS			
General controls	• Lock viewports • Switch to single/quad view • Take screenshot • Show/hide slice plane	• Lock viewports • Switch to single/quad view • Take screenshot • Show/hide slice plane	Identical
2d CT image controls	• Pan • Window • Level • Scroll slice • Zoom	• Pan • Window • Level • Scroll slice • Zoom	Identical
3D map controls	• Rotate (clockwise, counterclockwise, free rotate) • Pan • Zoom	• Rotate (clockwise, counterclockwise, free rotate) • Pan • Zoom	Identical

Compared to the predicate (AiORTA Plan v1.1), the subject device (AiORTA Plan 2.0) has a few technical differences. These include the option for users to receive the direct output of the automated analysis without initial correction by a ViTAA analyst, with physicians retaining complete control of corrections and edits. Regions of interest are also extended to include the external iliac arteries and a large portion of the descending aorta. Image

analysis tools for users are expanded, allowing manual correction of all measures produced by the software. Finally, additional information is provided in the form of C-Arm calculations and institution-based device suggestions derived from a lookup table.

While the subject device, AiORTA Plan 2.0, contains some additional software features as compared to the predicate, these features serve only to give clinicians additional information and control in their analysis and do not raise new questions of safety or effectiveness.

Performance Testing

No additional performance testing was conducted for the AI/ML algorithms, as these are identical to those used by the predicate. Software changes included some additional verification and validation tests, which are summarized in the attachment "AiORTA Plan V2.0 Change Traceability Summary". Details on software changes and V&V are also included in the attached software documentation.

Conclusion

The information submitted in this premarket notification supports the safety and effectiveness of the AiORTA – Plan v2.0 as compared to the predicate device, AiORTA - Plan v1.1 in context of the intended use and labelling of the device.