October 30, 2025

ViTAA Medical Solutions Inc.
Marc Saab
Managing Director
BML Health Inc.
626 rue de la Congregation
Montreal, QC H3K2J2
Canada

Re: K250337
Trade/Device Name: AiORTA - Plan
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 4, 2025
Received: February 6, 2025

Dear Marc Saab:

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, PhD
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

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)*

K250337

Device Name

AiORTA - Plan

Indications for Use *(Describe)*

The AiORTA - Plan tool is an image analysis software tool for volumetric assessment. 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter	ViTAA Medical Solutions Inc. 2590 Rue de Rouen Montreal, QC, H2K 1M6
Contact	Mitchel Benovoy mitchelbenovoy@vitaamedical.com +1-514-655-9952
Preparation Date	February 6th, 2025

Device Information

Trade Name	AiORTA - Plan
510(k) Number	K250337
Regulation Name	Medical image management and processing system
Common Name	Automated radiological image processing software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Device Classification	Class II
Classification Panel	Radiology

Predicate Device

Trade Name	iNtuition-Structural Heart Module
510(k) Number	K191585
Regulation Name	Medical image management and processing system
Common Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Device Classification	Class II
Classification Panel	Radiology

Reference Devices

In addition to the predicate device mentioned above, Simpleware ScanIP Medical by Synopsys (Northern Europe) Ltd. (K203195) and TeraRecon Aorta.CT (1.1.0) by TeraRecon, Inc. (K243158) are identified as a reference devices to support the technological comparison for the volume measurement feature and establish acceptance criteria for landmark distance and segmentation accuracy.

Device Description

AiORTA - Plan 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 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 modules that are operated by a trained Analyst 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 Analyst plays a role in ensuring the quality of the outputs. However, 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. A trained Analyst performs quality control of the segmentations, making any necessary revisions to ensure accurate outputs.
- *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 containing key measurements and a 3D Anatomy Map providing multiple views of the abdominal aorta and its landmarks.
- *Web application integration:* the outputs, including the segmented CT masks, 3D visualizations, and reports, 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:

- *Segmentation review and correction:* Clinicians can review the resulting segmentations from the Analysis Pipeline segmentations 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 either the default key measurements computed by the Analysis Pipeline or custom measurements and screenshots captured during review.

Indications for Use

The AiORTA - Plan tool is an image analysis software tool for volumetric assessment. 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.

Comparison of Indications for Use

Table 1: Indications for Use Comparison

Subject Device: AiORTA - Plan	**Predicate Device: iNtuition-Structural Heart Module (K191585)**
The AiORTA - Plan tool is an image analysis software tool. It provides visualization and measurements based on 3D reconstruction, computed from cardiovascular CTA scans. The 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,	iNtuition-Structural Heart Module is a software solution that is intended to assist Cardiologists, Radiologists and Clinical Specialists with the visualization and measurements of structures of the heart and vessels. iNtuition-Structural Heart Module enables the user to: • Visualize and measure (diameters, lengths, angles, areas and volumes) structures of the heart and vessels for pre-operative planning

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.	and sizing for cardiovascular interventions and surgery, and for post-operative evaluation. • Quantify calcium (volume, density).iNtuition-Structural Heart Module has the following tools and features that facilitate: • Automatic and manual centerline detection. • Segmentation of cardiovascular structures. • Measurement tools (diameters, lengths, areas, volumes, angles) for the dimensions of vessels and structures. • Calcium quantification and scoring. • Various visualization techniques: 2D/3D/4D visualization, MPR, Curved MPR, Stretched MPR, MIP, MinIP, Raysum and MAR. • Capture and Report.

The intended use of the AiORTA - Plan tool has a more narrowly defined scope compared to the iNtuition-Structural Heart Module, focusing specifically on supporting pre- and post-operative planning for aortic interventions. In contrast, the iNtuition-Structural Heart Module has a broader intended use, supporting visualization and measurement of various heart and vessel structures for a wider range of cardiovascular interventions. It includes additional features such as calcium quantification.

Both devices are intended for use in pre-operative evaluation, planning and sizing for cardiovascular intervention and surgery, and for post-operative evaluation. The differences in intended use between the subject and predicate device, are not critical to the intended use of the subject device, and the differences do not affect the safety and effectiveness of the subject device when used as labeled.

Comparison of Technological Characteristics

Table 2: Substantial Equivalence Comparison

Device Characteristic	**Subject Device: AiORTA - Plan**	**Predicate Device: iNtuition-Structural Heart Module (K191585)**
Manufacturer	ViTAA Medical Solutions Inc.	TeraRecon Inc.
Classification	21 CFR 892.2050	21 CFR 892.2050
Product code	QIH	LLZ
Intended end-user	Healthcare Practitioner	Healthcare Practitioner
Anatomical scope	Abdominal aorta	Aorta, aortic valves, mitral valve, pulmonic valve, atria and atrial appendages, and ventricles
Image source	Cardiovascular CTA scans	CT, MR, Nuc, PET, Angio, US/Echo, SPECT scans
Operating system	Microsoft Windows	Microsoft Windows
System configuration	Web application	Server or workstation
Analysis workflow	Semi-automatic analysis pipeline requiring input from ViTAA Analysts.	Fully automated analysis performed in real-time within the software.

Device Characteristic	Subject Device: AiORTA - Plan	Predicate Device: iNtuition-Structural Heart Module (K191585)
Vessel Geometry Measurement Tools	Provides tools for measuring vessel geometry, including diameters, lengths, and volumes.	Provides tools for measuring vessel geometry, including diameters, lengths, volumes, areas, and angles.
Segmentation	Semi-automatic segmentation using automasking algorithm. End-users (clinicians) able to review and modify segmentations as needed.	Automatic and manual segmentation available within the software, with end-users (clinicians) able to edit and adjust segmentations as needed.
Centerline detection	Automatic centerline detection within the analysis pipeline.	Both automatic and manual centerline detection are offered, with the ability to edit and refine the centerline by the end-user.
Change in Geometric Analysis	Reports automated measurements describing changes between two studies.	Not available
Storage of results	- Report in PDF format - Viewports: Session state	- Structured reporting with xml, text, xls output - Word and html report - DICOM SC - Workflow scenes: restore saved state
Viewpoint controls	-General controls (lock viewpoints, switch to single/quad view, etc.) -2D CT image controls (pan, window, level, etc.) -3D map controls (rotate, pan, zoom)	Identical to or more extensive than subject device

Substantial Equivalence

The detailed analysis above demonstrates substantial equivalence of AiORTA - Plan to the previously cleared iNtuition-Structural Heart Module software (K191585). There are minor differences in intended use and technological characteristics between subject and predicate devices; however, the differences are not critical to the intended clinical use of the subject device.

The technological differences include:

1. System configuration: The subject device is configured as a web-based application, whereas the iNtuition-Structural Heart Module is typically installed on a server or workstation. Cybersecurity risks for the web-based configuration of the subject device have been extensively analyzed and mitigated.
2. Analysis workflow: The subject device utilizes ViTAA Analyst intervention and operates on a longer timeline, while the predicate device provides real-time analysis. Risks related to delays in analysis availability have been assessed within the risk management file, ensuring that they remain acceptable.
3. Change in geometric analysis: The subject device provides automated measurements that quantify changes in vessel geometry between two studies. This functionality is not available in the

predicate device. The subject device's automated vessel geometry measurements have been validated and are considered acceptable.

The assessment of device differences shows that AiORTA - Plan does not raise new or different questions of safety and effectiveness. The test results obtained from verification and validation activities (non-clinical testing) in accordance with current standards and regulatory guidance indicate a favorable performance and safety profile of the subject device. The test results also confirm that the technological differences with the predicate device do not raise new or different questions of safety and effectiveness of the subject device.

Testing and Performance Data

Software Verification and Validation

The AiORTA - Plan medical software underwent comprehensive verification and validation in accordance with IEC 62304 to ensure functionality, performance, and compliance. Testing included automated and manual testing of the Analysis Pipeline and Web Application, end-to-end integration testing of the complete system workflow, and cybersecurity assessments to ensure vulnerabilities are identified and risks are mitigated, data is protected, and compliance is verified against industry standards.

Moreover, critical algorithms were verified by comparing their outputs to ground truth data to ensure accuracy and reliability. Algorithms were first verified using synthetic data to remove the influence of external factors and isolate algorithm performance. Subsequent verification was performed using clinical data, including aortic aneurysm cases from both US and Canadian clinical centers, with outputs compared to clinical ground truth.

- **Auto-segmentation masks:** Masks generated by the Analysis Pipeline from input CT data (prior to analyst correction) were verified by comparing them to annotations approved by 3 US-based board-certified Radiologists, demonstrating the performance of the auto-masking algorithm independently of human intervention.
  Acceptance criteria:
  - *≥ 80% Dice coefficient achieved for the aortic wall and aortic lumen masks*
  - *Key anatomical landmarks were identified within 5mm of ground truth*

  Results:
  - *Overall Mean Dice coefficient of 89% achieved for the aortic wall*
  - *Overall Mean Dice coefficient of 89% achieved for the aortic lumen masks*
  - *Landmark identification:*
    - *Celiac artery proximal position: Mean distance 2.47mm*
    - *Renal arteries distal position: Mean distance 3.51mm*

- **Diameters and lengths**: Maximum or average diameters within a specified region of interest (ROI), as well as lengths between specific landmarks, were compared against annotations from 3 US-based board-certified Radiologists. Measurements computed by the Analysis Pipeline were based on segmentations that underwent Analyst review and correction, ensuring that the verification reflects real-world use conditions.

Acceptance criteria:

- *Mean absolute error ≤ 6.0mm for length*
- *Mean absolute error ≤ 2.3mm for diameters*

Results:

- *Length:*
  - *Renal artery to aortic bifurcation: mean absolute error 5.3 mm*
  - *Renal artery to left iliac bifurcation: mean absolute error 7.0mm*
  - *Renal artery to right iliac bifurcation: mean absolute error 6.6mm*
- *Diameter:*
  - *Aortic wall max: mean absolute error 2.0 mm*
  - *Aortic wall at renal artery: mean absolute error 2.1 mm*
  - *Aortic wall at left iliac bifurcation: mean absolute error 1.9mm*
  - *Aortic wall at right iliac bifurcation: mean absolute error 2.5 mm*

For measurements that did not meet the initial acceptance criteria, a mean pairwise absolute difference (MPAD) comparison was performed to assess consistency between experts and between the device and experts. Specifically, the expert-expert MPAD was computed as the mean of ([expert 1 - expert 2], [expert 1 - expert 3], [expert 2 - expert 3]), and device-expert MPAD was computed as the mean of ([device - expert 1], [device - expert 2], [device - expert 3]).

The device-expert MPAD was smaller than the expert-expert MPAD, supporting the overall acceptability of the device's measurements.

	Expert-expert MPAD	Device-expert MPAD
Length: renal to left iliac bifurcation	7.1mm	6.9mm
Length: renal to right iliac bifurcation	10.4mm	9.6mm
Diameter: wall right iliac	2.7mm	2.5mm

- **Volumes** were compared against results from the reference device, Simpleware ScanIP Medical, using analyst revised segmentations as input data for both devices to ensure a fair comparison.
  Acceptance criteria:
  - *Mean absolute error ≤ 1.8 mL*
  Results across 40 CT scans:
  - Volume of the Wall: *Mean absolute error* 0.00242 mL, standard deviation of errors: 0.00280 mL
  - Volume of the Lumen: *Mean absolute error* 0.00257mL, standard deviation of errors: 0.00300mL

All software verification and validation activities were successfully completed. Known anomalies were documented and assessed, and their impact was determined not to affect the safety or effectiveness of the device for its intended use.

Human Factors Engineering

Human Factors Engineering considerations were applied throughout the design and development process, following the guidelines specified in IEC 62366. A comprehensive Use Related Risk Analysis was conducted to identify and mitigate potential risks associated with the interaction between users and the software and external usability validation testing was performed by US based clinical specialists (board-certified radiologists and vascular surgeons). The results of the human factors validation study demonstrated that intended users can safely and effectively perform all critical tasks associated with AiORTA - Plan under expected use conditions. Observed use errors were analyzed and determined not to present unacceptable risk. Therefore, the study concludes that AiORTA - Plan does not introduce new or increased use-related risks compared to the predicate device.

Cybersecurity

Cybersecurity testing included verification and validation of cybersecurity controls including manual and automated testing, vulnerability testing, and penetration testing. Post-market monitoring processes have been established to detect and address new vulnerabilities.

Summary of Clinical Performance Tests

AiORTA - Plan did not require clinical studies to demonstrate substantial equivalence to the predicate device.

Conformance Standards

The device complies with the following conformance standards:

- ISO 14971: 2019 Application of risk management to medical devices
- IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes
- IEC 62366 Medical devices - Part 1: Application of usability engineering to medical devices

Conclusions

The information submitted in this premarket notification, including the performance testing and predicate device comparison, support the substantial equivalence of AiORTA - Plan to the predicate device in context of the intended use and labelling of the device.