Ventripoint Diagnostics Ltd.
% Zhang Cheng
Regulatory Affairs and Quality Manager
18 Hook Ave, Unit 101
Toronto, ON M6P1T4
CANADA

February 26, 2025

Re: K241222
Trade/Device Name: Ventripoint Medical System Plus (VMS+) 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: March 6, 2024
Received: June 3, 2024

Dear Zhang Cheng:

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.
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)*
K241222

Device Name
Ventripoint Medical System Plus (VMS+) 4.0

Indications for Use *(Describe)*
The VMS+ 4.0 system is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.

The VMS+ 4.0 system is indicated for use where Left Ventricle (LV), Right Ventricle (RV), Left Atrium (LA), and Right Atrium (RA) volumes and ejection fractions are warranted or desired.

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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"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."

Section 5: Traditional 510(k) Summary

Date:	January 17, 2025
Submitter:	Ventripoint Diagnostics Ltd. 18 Hook Ave, Unit 101 Toronto Ontario M6P 1T4 Canada
Contact Person:	Aaron Zhang RA/QA Manager azhang@ventripoint.com Tel: 416-848-4156
Device Name	Ventripoint Medical System Plus (VMS+) 4.0
Classification:	Regulatory Class: II Review Category: Tier II Classification Panel: Radiology Regulation Number: 892.2050 Classification Product Code: QIH Secondary Product Code: LLZ

A. Legally Marketed Predicate Device

Device Name	Ventripoint Medical System Plus (VMS+) 3.0
510k Number:	K191493
Common Name:	Radiological Image Processing System
Classification:	Regulatory Class: II Review Category: Tier II Classification Panel: Radiology Regulation Number: 892.2050

B. Device Description

The Ventripoint VMS+ 4.0 System is a medical imaging device designed to assist clinicians in evaluating cardiac function through 3D reconstruction of heart chambers. It uses a Knowledge-Based Reconstruction (KBR) algorithm to recreate the heart's shape by capturing 2D ultrasound images at specific angles and referencing a database of MRI heart shape catalogs. The reconstructed 3D heart models are used to calculate volumes of any of the four chambers at end-diastolic and/or end-systolic phases. The software can also be installed on a separate workstation to import 3D datasets, MRI studies, and VMS+ studies.

The system employs user-driven anatomical control point placement to generate 3D models. Users manually adjust control points based on an anatomical template aligned with the patient's ultrasound images. An edge detection algorithm refines these points to match detected anatomical boundaries, ensuring model precision.

The VMS+ system includes a hardware stand with a computer, position sensors to track the 3D orientation of the ultrasound transducer and patient movement, and software to handle image capture, landmark placement, and reconstruction. By leveraging its sensor system and statistical shape analysis, the VMS+ transforms 2D ultrasound data into accurate 3D models. The workflow takes approximately 15 minutes and provides detailed volumetric data and reports for clinical review.

C. Indication for Use

The indications for use for the subject device are the same as the predicate device.

The VMS+ 4.0 system is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing.

The VMS+ 4.0 system is indicated for use where Left Ventricle (LV), Right Ventricle (RV), Left Atrium (LA), and Right Atrium (RA) volumes and ejection fractions are warranted or desired.

D. Verification and Validation Summary

The verification and validation of the existing and new features of the VMS+ demonstrate that the VMS+ 4.0 performs as intended, specifications conform to user needs and intended uses, and that the requirements implemented can be consistently fulfilled.

All test reports were successful according to the acceptance criteria. The verification and validation were performed with software versions and hardware units that are considered equivalent to the final version of the product, as warranted by 21 CFR 820.30(g) and with the user interface as planned for the release.

E. Technological Characteristics

The subject device, VMS+ 4.0, has similar technological characteristics as the predicate device, VMS+ 3.0 (K191493) with regard to the intended use, indications for use, operational environment, software, operating system, operating principle, technology, and performance. The modifications to the hardware/software have been tested for safety and effectiveness and have been determined to be safe and effective.

F. Performance Data

Bench Testing

Performance bench testing of the modified device was completed to verify that the modified device was substantially equivalent in performance specifications to the previously cleared device. Predefined acceptance criteria were applied during testing and were met. The verification test results demonstrate that the system software performs as intended and all requirements are met.

Software Verification and Validation

Software verification and validation testing were conducted, and documentation was provides as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered to have a basic documentation level since software failures or flaws are do not present a hazardous situation with a probable risk of death or serious injury to anyone within the environment of use.

The verification and validation of the existing and new features of the VMS+ 4.0 software demonstrate that the VMS+ 4.0 software performs as intended, specifications conform to user needs and intended uses, and that the requirements implemented can be consistently fulfilled.

All test reports were successful according to the acceptance criteria. The verification and validation were performed with software versions and hardware units that are considered equivalent to the final version of the product, as warranted by 21 CFR 820.30(g) and with the user interface as planned for the release.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the VMS+ 4.0 device. The system complies with the applicable requirements of IEC 60601-1 standard for safety and essential performance and IEC 60601-1-2 standard for electromagnetic compatibility.

User Validation

An internal user validation study was performed to demonstrate that the modified device does not negatively impact user performance for anatomical point processing. From 160 ultrasound images of the right ventricle, the study estimated the proportion of images for each software where all anatomical points within the image would be finalized, by the user, within its respective expert consensus region. The test criteria were met, demonstrating that user performance for final point localization using VMS+ 4.0 was at least as good as the predicate, when used by the same users for the same imaging set. However, the study did not evaluate accuracy of the initial point placed by the AI software, which should only be viewed as a first guess and used with caution.

Cybersecurity

Cybersecurity testing was performed as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". This included both internal cybersecurity validation and external penetration testing to ensure that any existing vulnerabilities were discovered and addressed, and that the device is cyber safe.

G. Safety and Effectiveness

VMS+ 4.0 is a non-invasive, non-significant risk technology. The modifications to the cleared VMS+ user interface, including GUI and position tracking system do not introduce new questions concerning safety or effectiveness and is therefore substantially equivalent to the predicate.

H. Technological Characteristics

As shown in the device comparison below, the technological characteristics of the subject VMS+4.0 remain the same as the previously cleared device under K191493 . The similarities and differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate. Both the subject and predicate devices have the same intended an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS+ 4.0 system is indicated for use where Left Ventricle (LV), Right Ventricle (RV), Left Atrium (LA), and Right Atrium (RA) volumes and ejection fractions are warranted or desired.

The only change in the VMS+ 4.0 software compared to the predicate is adding an additional method for placing the first guesses for anatomical control points that are updated to a final location manually by a user and minor hardware modification to remove magnet from the transmitter and sensor. The automated control point first guess feature only provides an alternate method for obtaining first guesses for the location of the control points and users are still expected to update control point location in the same manner as the predicate before being used for further analysis. These proposed modifications are verified to ensure overall performance remains the same as the predicate with acceptable results.

Feature/Characteristic	**Predicate Device Ventripoint Medical System Plus (VMS+) 3.0 (K191493)**	**Subject Device Ventripoint Medical System Plus (VMS+) 4.0**	**Comparison**
Indications for Use	The VMS+ is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS+ is indicated for use where Left Ventricle (LV), Right Ventricle (RV), Left Atrium (LA), and Right Atrium (RA) volumes and ejection fractions are warranted or desired.	The VMS+ is an adjunct to existing ultrasound imaging systems and is intended to record, analyze, store and retrieve digital ultrasound images for computerized 3-dimensional image processing. The VMS+ is indicated for use where Left Ventricle (LV), Right Ventricle (RV), Left Atrium (LA), and Right Atrium (RA) volumes and ejection fractions are warranted or desired.	Same
Technological Characteristics			
Software based analysis tool	Yes	Yes	Same
Knowledge-Based Reconstruction Algorithm	Yes	Yes	Same
3D Visualization	Generates a 3D surface model of the 4 chambers and	Generates a 3D surface model of the 4 chambers and	Same

Feature/Characteristic	Predicate Device Ventripoint Medical System Plus (VMS+) 3.0 (K191493)	Subject Device Ventripoint Medical System Plus (VMS+) 4.0	Comparison
	accompanying volume measurement.	accompanying volume measurement.	
Measurements	End-systolic volumes (EDV, ESV), Ejection Fractions (EF), Stroke Volumes and Cardiac Outputs	End-systolic volumes (EDV, ESV), Ejection Fractions (EF), Stroke Volumes and Cardiac Outputs.	Same
Acquisition Workflow	Executing on a computer, processes data acquired by the sensor system in conjunction with the output from the ultrasound equipment, to enable tracking of anatomic landmark points from the 2D images and conversion of those points into 3D data points.	Executing on a computer, processes data acquired by the sensor system in conjunction with the output from the ultrasound equipment, to enable tracking of anatomic landmark points from the 2D images and conversion of those points into 3D data points.	Same
Points placement	Requires placement of anatomic landmarks on the 2D images. On-screen guide is provided to user for point placement first guesses. User must manually adjust first guess point placements as required. Landmarks are then used to build an accurate 3D constructed shape mesh (defined by vertices, edges, and faces).	Requires placement of anatomic landmarks on the 2D images. On-screen guide is provided to user for point placement first guesses. Alternatively, automated point placement first guesses can be generated via a button press. User must manually adjust first guess point placements as required. Landmarks are then used to build an accurate 3D constructed shape mesh (defined by vertices, edges, and faces).	VMS+ 4.0 is equivalent to VMS+ 3.0. The automated control point first guess placement is added to improve user workflow efficiency. Users must still modify/confirm control point placement after an automated first guess. Internal user validation of the final location of control points using the on-screen guide versus automated first guesses was assessed. Additionally, verification tests were performed against doctors' point placement. Thus, the difference does not raise different questions of safety and effectiveness.

Feature/Characteristic	Predicate Device Ventripoint Medical System Plus (VMS+) 3.0 (K191493)	Subject Device Ventripoint Medical System Plus (VMS+) 4.0	Comparison
Location of KBR catalogue	Knowledge-based reconstruction located locally on the system, which accepts the 3D data points generated through the use of the position sensor system and provides the computation engine for generating a 3D surface construction of the four chambers and accompanying volume measurement and ejection fractions of the four chambers of the four chambers of the heart, either at end-diastolic and/or end-systolic.	Knowledge-based reconstruction located locally on the system, which accepts the 3D data points generated through the use of the position sensor system and provides the computation engine for generating a 3D surface construction of the four chambers and accompanying volume measurement and ejection fractions of the four chambers of the four chambers of the heart, either at end-diastolic and/or end-systolic.	Same
Software application types	Console (system) and Workstation (standalone)	Console (system) and Workstation (standalone)	Same
Hardware data acquisition system	Touchscreen for image capture, a video-input connector to receive image data from an ultrasound machine, off-the-shelf real-time video capture card to receive image data from an ultrasound machine, and 3D positional tracking system to receive position and orientation information.	Touchscreen for image capture, a video-input connector to receive image data from an ultrasound machine, off-the-shelf real-time video capture card to receive image data from an ultrasound machine, and 3D positional tracking system to receive position and orientation information.	Same

Feature/Characteristic	Predicate Device Ventripoint Medical System Plus (VMS+) 3.0 (K191493)	Subject Device Ventripoint Medical System Plus (VMS+) 4.0	Comparison
3D tracking/positional system	Magnetic-based; free-hand scanning; consisting of mechanical arm, transmitter, ultrasound transducer sensor, and associated electronics.	Magnet-free; free-hand scanning; consisting of ultrasound transducer sensor, transmitter/sensor on patient, and associated electronics.	VMS+ 4.0 is equivalent to VMS+ 3.0 with the only difference being that the magnet has been removed from transmitter/sensor as an improvement. The way in which the device operates remains the same; both systems are free-hand scanning. In addition, the performance of the new device is the same as the predicate device. Thus, the difference does not raise different questions of safety and effectiveness.
Patient contacting components	Surface device; intact skin; A-limited (<24h)	Surface device; intact skin; A-limited (<24h)	Same
3D Echo and MRI functionality	Can import 3D echo and MRI studies for volumetric analysis.	Can import 3D echo and MRI studies for volumetric analysis.	Same
Software controls	The software components are responsible for providing the user with controls for managing the hardware operation, capturing ultrasound images, marking up images with key anatomical features, invoking the reconstruction algorithm, displaying the resulting construction and generating the corresponding report.	The software components are responsible for providing the user with controls for managing the hardware operation, capturing ultrasound images, marking up images with key anatomical features, invoking the reconstruction algorithm, displaying the resulting construction and generating the corresponding report.	Same
Power requirements	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz	Power requirements: AC :100V- 240V, Frequenzy:50-60Hz	Same
Image data format	Original VMS+ and DICOM format	Original VMS+ and DICOM format	Same

I. Substantial Equivalence Conclusion

The VMS+ 4.0 with accessories and proprietary software has been verified and validated according to Ventripoint procedures for product design and development. The information provided by Ventripoint in this Traditional 510(k) application supports the claim of substantial equivalence to the predicate device (K191493) with regard to both intended use and technological characteristics.