Ventripoint Diagnostics, Ltd.
℅ Desmond Hirson
President
2 Sheppard Avenue East, Suite 605
Toronto, Ontario M2N 5Y7
CANADA

October 16, 2019

Re: K191493
Trade/Device Name: Ventripoint Medical System Plus (VMS+) 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, IYN, IYO, ITX
Dated: September 13, 2019
Received: September 16, 2019

Dear Desmond Hirson:

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,

For

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191493

Device Name
Ventripoint Medical System Plus (VMS+) 3.0

Indications for Use *(Describe)*

The VMS+ 3.0 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+ 3.0 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.

***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."*

# K191493

## Section 3: 510(k) Summary

| | |
|---|---|
| **Date:** | September 13, 2019 |
| **Submitter:** | Ventripoint Diagnostics Ltd.<br>2 Sheppard Avenue East, Suite 605<br>Toronto, Ontario M2N 5Y7 |
| **Contact Person:** | Desmond Hirson<br>President<br>dhirson@ventripoint.com<br>Tel: 416-848-4156 |
| **Device Name** | Ventripoint Medical System Plus (VMS+) 3.0 |
| **Common Name:** | Diagnostic Ultrasound Image Analysis System |
| **Classification:** | Regulatory Class: II<br>Review Category: Tier II<br>Classification Panel: Radiology |
| **Classification Names:** | Picture archiving and communications system 892.2050 90 LLZ<br>Ultrasonic pulsed doppler imaging system 892.1550 90 IYN<br>Ultrasonic pulsed echo imaging system 892.1560 90 IYO<br>Diagnostic ultrasonic transducer 892.1570 90 ITX |

### A. LEGALLY MARKETED PREDICATE DEVICE

| | |
|---|---|
| **Device Name** | GE EchoPAC |
| **510(k) Number** | K150085 |
| **Common Name:** | Picture Archiving and Communications System |
| **Classification:** | Regulatory Class: II<br>Review Category: Tier II<br>Classification Panel: Radiology<br>Ultrasonic Pulsed Doppler Imaging System 892.2050 90 LLZ |

### B. LEGALLY MARKETED REFERENCE DEVICE

| | |
|---|---|
| **Device Name** | Ventripoint Medical System Plus (VMS+) |
| **510(k) Number** | K173810 |
| **Common Name:** | Diagnostic Ultrasound Image Analysis System |
| **Classification:** | Regulatory Class: II<br>Review Category: Tier II<br>Classification Panel: Radiology<br>Ultrasonic Pulsed Doppler Imaging System 892.1550 90-IYN |

## C. DEVICE DESCRIPTION

The VMS+ was cleared under 510(k) (K173810) for use in evaluation where Right Ventricle (RV), Left Ventricle (LV), Right Atrium (RA), and Left Atrium (LA) volumes and ejection fractions are warranted or desired. The modified VMS+ (VMS+ 3.0) has the same operating principle and employs the same fundamental scientific technology to that of the cleared device.

## D. INTENDED USE/INDICATIONS FOR USE

The VMS+ 3.0 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+ 3.0 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.

## E. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE REFERENCE DEVICE

The VMS+ 3.0 is substantially equivalent to the primary predicate device, GE EchoPAC (K150085) and the reference device, Ventripoint Medical System Plus (VMS+) (K173810) with regard to both the intended use and technological characteristics.

As with the primary predicate device, VMS+ 3.0 provides annotation, analysis, measurement, report generation, communication, storage and retrieval of ultrasound images that are acquired via any ultrasound imaging system, for cardiology ultrasound applications.

Using the Knowledge-Based Reconstruction (KBR) algorithm and capturing 2D ultrasound images at specific angles and locations to recreate the shape of a heart is the technological principle for both the subject and predicate devices. It is based on the use of the constructed heart information to calculate volumes of any one of the four chambers, either at end-diastolic and/or end-systolic.

The VMS+ 3.0 has the same intended use and provides the same technological characteristics in terms of operational environment, software, operating system, operating principle, and performance when compared to the reference device.

At a high level, the subject and reference devices are based on the following same technological elements:

- Knowledge-based reconstruction algorithm. Requires placement of anatomic landmarks on the 2D images. Landmarks are then used to build an accurate 3D constructed shape mesh (defined by vertices, edges, and faces).

- 3D visualization and calcs: Generate a 3D surface model of the 4 chambers of the heart and calculate accompanying volume measurement.

- Executing on a computer, processes data acquired by a sensor system in conjunction

with the output from the ultrasound equipment, to enable tracking anatomic landmark points from the 2D images and conversion of those points into 3D data points.

- Windows OS 7 and 10 based analysis system
- 3D tracking/positional system is magnetic-based; free-hand scanning
- Console (system) and Workstation (standalone) software
- Patient contacting components for image acquisition
- Measurement and analysis technique: Record the ultrasound image sequences from the secondary video output of the 2D ultrasound machine and tracks the ultrasound transducer's 3D spatial coordinates during the imaging session by utilizing a 3D tracking system connected to the ultrasound transducer.
- 3D Echo and MRI functionality
- Original VMS+ and DICOM image data formats
- Software functionality: 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 following technological differences exist between the subject and reference devices:

- Knowledge-based reconstruction located locally on the system whereas for the predicate device, the knowledge-based reconstruction is located on a Microsoft Windows Server and accessible to the data acquisition tool over the internet
- Use of touchscreen and mouse as input devices
- Use of touchscreen for image capture and general user interface
- Medical grade computer mounted to a medical grade variable height roll stand
- User manually selects the End Diastolic and End Systolic frames whereas the predicate device automatically determined the first End Diastolic frame.
- The magnetic transmitter which acts as the reference point from which position and orientation has been moved closer to the patient.
- Scan plane adjustment for minor adjustment of the plane position obtained form the position sensors.
- User can both send to PACS and retrieve from PACS

**F. PERFORMANCE DATA**

The following performance data were provided in support of the substantial equivalence determination:

**Biocompatibility Testing**

Biocompatibility testing was conducted on patient contacting components of the VMS+ 3.0 device, including evaluation tests for cytotoxicity, sensitization, and irritation of intracutaneous reactivity. The components comply with the ISO 10993-1 standard.

**Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the VMS+ 3.0 device. The system complies with the IEC 60601-1 standard for safety and essential performance and IEC 60601-1-2 standard for electromagnetic compatibility.

**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, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since failures or latent design flaws are unlikely to result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

The verification and validation of the existing and new features of the VMS+ 3.0 demonstrate that the VMS+ 3.0 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.

**Nonclinical Performance Bench Study**

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 reference device. Predefined acceptance criteria were applied during testing and were met. The test results generated demonstrate that the device is as safe, as effective, performs as intended and as well as the predicate device (i.e. delivers volume measurements that are equivalent in accuracy when compared with volumes obtained using the legally marketed VMS+.

**Animal Study**

No animal study was required to support substantial equivalence for the subject device.

**Clinical Studies**

No clinical tests were conducted to support substantial equivalence for the subject device.

## G. Conclusions

### Device Similarities

Intended use and other key features are consistent with traditional clinical practice and FDA guidance. The VMS+ 3.0 product conforms to applicable medical device safety standards and compliance is verified through independent evaluation. The design and development process of the manufacturer conforms to 21 CFR 820 Quality System Regulation and ISO 13485:2016 quality system standards.

### Safety and Effectiveness

VMS+ 3.0 is a non-invasive technology. The modifications to the cleared VMS+ software and hardware do not introduce new questions concerning safety or effectiveness. and is therefore substantially equivalent to the predicate. Ventripoint Diagnostics Ltd. believes that VMS+ 3.0 is as safe and effective as the reference device and performs as well as the reference device.