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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

[Signature]
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known)
K173810

Device Name
Ventripoint Medical System Plus (VMS+)

Indications for Use (Describe)

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.

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
PRASstaff@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.”
A. Legally Marketed Predicate Device

The Ventripoint Medical System Plus (VMS+) is an adjunct system to existing ultrasound imaging systems with accessories and proprietary software. It is substantially equivalent to Ventripoint Medical System (K150628).

B. Device Description

The VentriPoint Medical System was cleared under 510(k) K150628 for use in right ventricle evaluation where RV volumes and ejection fractions are warranted or desired. This current submission is intended to expand system use to Left ventricle (LV), Right Atrium (RA), and Left Atrium (LA) volumes and ejection fractions. LV, RA, LA evaluation is accomplished by the addition of KBR heart catalogs containing a variety of heart models for each chamber. VMS+ employs the same fundamental scientific technology to that of the cleared device.

C. Intended Use
The VMS+ 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+ 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. Substantial Equivalence
The Ventripoint Medical System Plus (VMS+) is a system with accessories and proprietary software. It is substantially equivalent to Ventripoint Medical System IS-1 (K150628).

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics.

<table>
<thead>
<tr>
<th>Feature/Characteristic</th>
<th>Predicate Device VentriPoint Medical System IS-1 (K150628)</th>
<th>Submission Device VMS+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use/Indications for Use</td>
<td>The VMS 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 system is indicated for use where RV volumes and ejection fractions are warranted or desired.</td>
<td>The VMS+ 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+ 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.</td>
</tr>
</tbody>
</table>
Freehand scanning device & Yes & Yes \\
RV volume measurement & Yes & Yes \\
3-D Reconstruction & Knowledge Based Reconstruction database & Knowledge Based Reconstruction database \\
Software Based Analysis Tool & Yes & Yes \\
UL 60601-1 & Yes & Yes \\
UL 60601-2 & Yes & Yes \\
Windows OS based analysis system & Yes & Yes \\
Real-time Video Capture card & Yes & Yes \\
External ECG trigger & Yes & Yes \\
Pulsed DC 6DOF magnetic tracking system & Yes & Yes \\

E. Non-Clinical Tests

The device has been evaluated for electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The systems comply with the following voluntary standards:

<table>
<thead>
<tr>
<th>Reference No.</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 60601-1</td>
<td>IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance 3rd edition.</td>
</tr>
<tr>
<td>ISO 14971:2007</td>
<td>Medical devices – Application of risk management to medical devices</td>
</tr>
</tbody>
</table>

Performance bench testing of the LV, LA, and RA catalogues was completed to verify suitability for left ventricle, left atrium, and right atrium evaluation. Testing of the LV, LA, and RA catalogs consisted of a robust series of automated and manual testing to verify reconstruction accuracy.
F. Clinical Tests

The VMS+, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

G. Conclusion

Device Similarities

Intended use and other key features are consistent with traditional clinical practice and FDA guidance. The VMS+ 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 13485:2003 quality system standards.

Safety and Effectiveness

The VMS+ system is a non-invasive, non-significant risk technology.

The LV, LA, and RA catalogs do not raise different questions of safety or effectiveness that were not applicable to the predicate device. Ventripoint Diagnostics Ltd. believes that the VMS+ is as safe and effective as the predicate device.