



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

VentriPoint, Inc.
% Mr. Jim Bodtke
V.P. of Clinical Affairs and Development
1805 136th Place NE, Suite 101
BELLEVUE WA 98005

May 22, 2015

Re: K150628
Trade/Device Name: VentriPoint Medical System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: March 9, 2015
Received: March 11, 2015

Dear Mr. Bodtke:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

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

Enclosure

Section 4 Indications for Use Statement

Indications for Use

510(k) Number (if known): k150628

Device Name: VentriPoint Medical System

Indications for 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 RV volumes and ejection fractions are warranted or desired.

Prescription Use √
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVID)

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Section 5 510(k) Summary or 510(k) Statement

510(k) Summary

807.92(c)

SPONSOR**807.92(a)(1)**

Company Name: VentriPoint, Inc.
 Company Address: 1805 136th Place NE, Suite 101
 Bellevue, WA 98005
 Telephone: 206-283-0221
 Fax: 425-747-4163
 Contact Person: Jim Bodtke

Summary Preparation Date: 9 March, 2015

DEVICE NAME**807.92(a)(2)**

Trade Name: VentriPoint Medical System IS-1
 Common/Usual Name: Diagnostic Ultrasound Image Analysis System
 Classification Name: Ultrasonic Pulsed Doppler Imaging System

PREDICATE DEVICE**807.92(a)(3)**

Legally Marketed Equivalent Device

<i>510(k) #</i>	<i>Product</i>
K140153	VentriPoint Medical System

<i>Company</i>
VentriPoint, Inc

DEVICE DESCRIPTION**807.92(a)(4)**

The VentriPoint Medical System was cleared under 510(k) K140153 for use in adult patients with Pulmonary Arterial Hypertension. This current submission is intended to expand system use to right ventricle evaluation where RV volumes and ejection fractions are warranted or desired in patients other than those diagnosed with PAH. Right ventricle evaluation is accomplished by the addition of a KBR heart catalog containing a variety of heart models that are not specific to PAH. All other system operational characteristics remain unchanged from the cleared device.

DEVICE INTENDED USE**807.92(a)(5)**

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.

COMPARISON OF TECHNICAL CHARACTERISTICS

807.92(a)(6)

Parameters	VentriPoint Medical System	VentriPoint Medical System
510(k) Number	Expanded Use	K140153
Indications for Use	<p>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.</p> <p>The VMS system is indicated for use where RV volumes and ejection fractions are warranted or desired.</p>	<p>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 used to record a sequence of conventional cardiac 2-D ultrasound images with the transducer position recorded for each image acquired to compute right ventricular volumes and ejection fraction. Specific anatomic landmarks identified by the product user are transmitted by secure internet connection to a VMS server where 3-D assembly of the right ventricle in adult patients with Pulmonary Arterial Hypertension takes place using Knowledge Based Reconstruction (KBR). The results are then returned to the VMS system for display and further consideration or evaluation by the product user.</p>
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

NONCLINICAL TESTING

807.92(b)(1)

Performance bench testing of the RV catalog was completed to verify suitability for right ventricle evaluation where RV volumes and ejection fractions are warranted or desired in patients other than those diagnosed with PAH.

Testing of the RV catalog consisted of a robust series of automated and manual testing to verify reconstruction accuracy.

CLINICAL TESTING

807.92(b)(2)

Prior clinical testing was completed in adult Pulmonary Arterial Hypertension (PAH) patients which was the basis for pre-market notification K140153. This clearance demonstrated the substantial equivalence of VentriPoint Knowledge Based Reconstruction (KBR) with volumes derived from cardiac MRI.

Development of the RV catalog was conducted according to VentriPoint established procedures in the same way as the PAH catalog that was cleared as part of K140153. Therefore additional human clinical trials were not warranted.

CONCLUSION

807.92(b)(3)

Device Similarities

The proposed expanded use of the VMS system is substantially equivalent to the predicate device, K140153, with the addition of a RV catalog that allows evaluation of RV volumes and ejection fractions in patients other than those diagnosed with PAH. All operational characteristics of the VMS system remain unchanged from the cleared device.

Safety and Effectiveness

The VMS system is a non-invasive, non-significant risk technology. No adverse events were reported during previous clinical trials. Accuracy of the RV catalog was assessed through rigorous bench testing and has been cleared for use in Canada and Europe since April 2013. The RV catalog introduces no new questions concerning safety or effectiveness and is therefore substantially equivalent to the predicate device.