



Food and Drug Administration  
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August 10, 2017

Surge Cardiovascular  
% Korina Akhondzadeh  
Regulatory Consultant to Surge Cardiovascular  
KARA & Associates  
6965 El Camino Real, Suite 105-428  
Carlsbad, California 92009

Re: K170488

Trade/Device Name: Peak Left Ventricular Vent Cannula, 20 Fr.; Peak Left Ventricular Vent Cannula, 18 Fr; Peak Left Ventricular Vent Cannula, 16 Fr

Regulation Number: 21 CFR 870.4210

Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing

Regulatory Class: Class II

Product Code: DWF

Dated: June 15, 2017

Received: June 19, 2017

Dear Korina Akhondzadeh:

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,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K170488

Device Name  
Peak Left Ventricular Vent Cannula

Indications for Use (Describe)

The Peak Left Ventricular Vent Cannula is indicated for use in venting the left ventricle during cardiopulmonary bypass procedures for durations up to 6 hours. The entrance is made at the juncture of the right superior pulmonary vein with the left atrium and passing through the mitral valve.

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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## 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

### I. SUBMITTER

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#### Official Correspondent

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**Date Prepared:** June 15, 2017

### II. DEVICE

Device Name:	Peak Left Ventricular Vent Cannula
Common/Usual Name:	Left Ventricular Vent
Classification Name:	Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass (21 CFR 870.4210)
Product Code:	DWF
Class:	II

### III. PREDICATE DEVICE

#### Primary Predicate Device

Curved Left Heart Vent Catheter, K0964194

#### Secondary Predicate Devices

DLP Left Heart Vent Catheter, K834352  
Malleable Vent Catheter, K981601

This predicate devices have not been subject to a recall.

#### **IV. DEVICE DESCRIPTION**

The Peak Left Ventricular Vent Cannula is a single lumen, PVC cannula intended for use in venting the left ventricle during cardiopulmonary bypass with entrance made at the juncture of the right superior pulmonary vein with the left atrium and passing through the mitral valve.

The 36cm Cannula has an open end at the distal tip and a series of side holes at the distal end of the cannula to allow for venting when inserted into the left ventricle. The device is designed with an open-ended smooth, tapered tip to minimize trauma to the tissues. The cannula body slip connector allows for connection to ¼" tubing for venting by the physician.

The device is supplied with a malleable PVC Introducer which has a length of stainless steel wire enclosed within the Introducer sheath. The Introducer has a smooth rounded tip at the distal end. When the Introducer is inserted into the cannula body, the luer hub fits into the internal diameter of the slip connector. When the luer hub is seated in the cannula slip connector, the smooth rounded end of the introducer extends beyond the open tip of the Cannula.

The device is provided sterile and is intended for single-use.

#### **V. INDICATIONS FOR USE**

The Peak Left Ventricular Vent Cannula is indicated for use in venting the left ventricle during cardiopulmonary bypass procedures for durations up to 6 hours. The entrance is made at the juncture of the right superior pulmonary vein with the left atrium and passing through the mitral valve.

#### **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

Both the Peak Left Ventricular Vent Cannula and the predicate devices are tubing sets with similar inlets and outlets for connection to source containers and vials or final medication containers. Both the subject and predicate devices are based upon the same technological elements:

The Peak Left Ventricular Vent Cannula and its predicate devices have similar technological characteristics:

- Device materials – Both subject and predicate devices have PVC cannula bodies
- Introducer design - The subject device and the California Medical Laboratories Malleable Vent Catheter have PVC Sheath over a malleable Stainless Steel core.
- Tip design – The subject device and the California Medical Laboratories Malleable Vent Catheter have an open ended cannula with open ended tip integrated with the catheter body.
- Depth markings – All devices have depth markings.
- Canula Sizes OD - Both Left Ventricular Vent Cannula and the Chase predicate device are available in 20 Fr. The subject device and the Medtronic DLP device are available in 16 Fr and 18 Fr.

- Side Openings – The subject device and predicate devices have holes at the distal end to allow for fluid flow through the cannula body.
- Cannula Length – Both the subject device and the Chase and DLP predicate devices are 15” long.
- Connector – All devices include a ¼” connector to allow for connection to a vacuum source.

## **VII. PERFORMANCE DATA**

### **Biocompatibility Testing**

The biocompatibility evaluation for the Peak Left Ventricular Vent Cannula device was conducted in accordance with FDA Guidance for Industry and FDA Staff – “Use of International Standard ISO 10993-1, “biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” June 16, 2016. Biocompatibility testing as required for External Communicating Devices, Circulating Blood, Limited Duration was conducted in accordance with cited guidances and standards.

The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Material-mediated pyrogenicity
- Hemocompatibility– Hemolysis Indirect and Hemolysis Direct
- Hemocompatibility – Thrombogenicity
- Hemocompatibility – Complement Activation
- Genotoxicity – Reverse Mutation Assay (Ames Test)
- Genotoxicity – Chromosomal Aberration

### **Performance Testing**

- Testing of Introducer Assembly of Device
- Simulated Bend/Removal of Introducer
- Flow and Simulated Use Flow Testing
- Simulated Pressure Testing
- Simulated Vacuum Testing
- Limit Testing for Connector Bond
- Limit Testing for Introducer Bond
- Limit Testing for Kink Resistance – Empty
- Limit Testing for Kink Resistance – Full
- Ink Adherence Testing
- Shipping/Distribution Studies for Packaging Integrity

## **VIII. CONCLUSIONS**

The testing conducted supports the substantial equivalence of the Peak Left Ventricular Vent Cannula to the predicate devices and demonstrates the Peak Left Ventricular Vent



Cannula performs as intended. The performance testing conducted demonstrates that the Peak Left Ventricular Vent Cannula performs substantially equivalent to the predicate devices. Both the Peak Left Ventricular Vent Cannula and the predicate devices have the same intended use and technological characteristics.