DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 18, 2015

InterValve, Inc.
c/o Ming Chew
Regulatory Consultant
Libra Medical Inc.
8401 73rd Avenue North, Suite 63
Brooklyn Park, Minnesota 55428

Re: K152150
Trade/Device Name: V8 Balloon Aortic Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: November 12, 2015
Received: November 13, 2015

Dear Mr. Chew:

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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K152150

Device Name
V8 Balloon Aortic Valvuloplasty Catheter

Indications for Use *(Describe)*
The V8 Balloon Aortic Valvuloplasty Catheter is indicated for Balloon Aortic Valvuloplasty.

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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# 1. 510(K) SUMMARY

## 1.1. ADMINISTRATIVE INFORMATION

**Date of Summary Preparation:** December 16, 2015

### 1.1.1. Contact Information


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### 1.1.2. Device Information

| | |
|---|---|
| **Trade Name** | V8 |
| **Common Name** | Balloon Aortic Valvuloplasty Catheter |
| **Classification Name** | Catheter, Balloon Aortic Valvuloplasty |
| **Classification Regulation** | 870.1255 |
| **Class** | II |
| **Panel** | Cardiovascular |
| **Product Code** | OZT |
| **FDA Documents Related to Modified Device** | None |

## 1.2. PREDICATE DEVICE

The modified device is substantially equivalent to the InterValve V8 Transluminal BAV Catheter (K150343).

## 1.3. DEVICE DESCRIPTION

The V8 Balloon Aortic Valvuloplasty Catheter features an hour glass shaped dilatation balloon on the distal end of a catheter. The catheter is inserted through a percutaneous entry site into the common femoral artery via an introducer sheath and advanced retrograde to the aortic valve. The catheter is always delivered over a guidewire. The balloon is then inflated to dilate the stenotic aortic valve leaflets in an effort to increase valve opening dimensions and systemic blood flow by improving leaflet mobility. The hour glass shaped balloon with the undersized waist segment is intended to minimize over-dilatation of the valve annulus while allowing the full dilation of the valve leaflet. The bulbous proximal balloon segment is appropriately sized for the patient's aortic root dimensions to maximize valve leaflet opening.

The V8 Balloon Aortic Valvuloplasty Catheter can be used as both a pre-dilatation and post-dilatation device for self-expanding transcatheter heart valves.

## 1.4. INTENDED USE

The V8 Balloon Aortic Valvuloplasty Catheter is intended to be used to dilate aortic valve tissue. There is no change in intended use from the V8 predicate device.

## 1.5. INDICATIONS FOR USE

The V8 Balloon Aortic Valvuloplasty Catheter is indicated for Balloon Aortic Valvuloplasty.

## 1.6. TECHNOLOGICAL CHARACTERISTICS

The V8 balloon is made of clear semi-compliant polymeric material. The balloon is available in four sizes (waist/bulb diameters of 17/22 mm, 19/24 mm, 21/26 mm and 23/28 mm). The waist of the hour glass balloon is sized such that it is smaller than the bulb diameter up to the rated burst pressure. The V8 balloon is intended to provide a means for dilation of stenotic aortic valve tissue while minimizing dilation of the aortic annulus by virtue of its hour glass shape.
The catheter is currently available in a 110 cm length and is compatible with a 12F introducer sheath. It is introduced through the femoral artery via the introducer sheath and tracked over a 0.035" wire. The catheter's inner shaft beneath the balloon is marked with radiopaque platinum iridium marker bands, two at the center of the waist, and one each at the outside edges of the proximal and distal balloon shoulders. The catheter is packaged in a heat sealed Tyvek pouch and provided sterilized. It is intended for single use only. These characteristics are identical to the predicate V8 device.

## 1.7. COMPARISON TO PREDICATE DEVICE

In comparison to the predicate device, the balloon bulb length has been reduced from 10mm to 8mm. All other technological characteristics remain the same.

## 1.8. PERFORMANCE DATA

Design verification was repeated because the balloon bulb length was modified.

**Table 1-1: Special Controls**

| Special Control Requirement | Evidence of Conformity |
|---|---|
| The device should be demonstrated to be biocompatible. | The proposed change does not affect the biocompatibility of the device. The biocompatibility test data were provided in the K123111 submission. There were no new materials added. |
| Sterility and shelf life testing should demonstrate the sterility of patient contacting components and the shelf-life of these components. | The sterile packaging and shelf carton are identical to the predicate V8 device. The worst case device is identical to the predicate device because it is larger with more material to sterilize. Therefore the sterility data provided previously is applicable. The sterilization validation test results provided in the 510(k) notification K123111 is applicable to this device.<br><br>Shelf life testing was not repeated because the design changes did not affect the validity of the shelf life testing done with the predicate V8 device. The material and manufacture of the device remains the same as the predicate. Shelf life testing data is provided in the K133607 submission. |
| Non-clinical performance evaluation of the device should demonstrate substantial equivalence in terms of safety and effectiveness for device delivery, inflation, deflation, and removal. | See below for summary of non-clinical performance tests. |
| In vivo evaluation of the device should demonstrate device performance, including the ability of the device to treat aortic stenosis. | The shape of the device has not changed and the principles of operation are also the same. The device dimensions are similar to the predicate device submitted in 510(k) notification K150343. |
| Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to use of the device. | The IFU contains “Potential Complications, Outcomes, Adverse Events” section. |

The following testing was performed to demonstrate substantial equivalence to the predicate device:

- Bond tensile strength
- Balloon rated burst pressure
- Balloon compliance (diameter vs. pressure)

## 1.9. SUBSTANTIAL EQUIVALENCE

The V8 device covered by this submission is substantially equivalent to the V8 predicate device. The device intended use has not changed and the design principles are the same. There has been no change to the materials or manufacture of the balloon.

The V8 device covered by this submission has the same intended use and the same technological characteristics as the previously cleared V8 predicate device. The differences between this device and the V8 predicate do not raise new questions of safety or efficacy.

## 1.10. CONCLUSION

The modified V8 Balloon Aortic Valvuloplasty Catheter is substantially equivalent to the predicate device (K150343).