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

April 3, 2015

Intervalve, Inc.
% Ming Chew
Regulatory Consultant
Libra Medical Inc.
8401 73rd Avenue North, Suite 63
Brooklyn Park, Minnesota 55428

Re: K150343
Trade/Device Name: V8 Transluminal BAV Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: March 3, 2015
Received: March 4, 2015

Dear Ming 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)*	
K150343	
Device Name	
V8 Transluminal BAV Catheter	
Indications for Use (*describe*)	
The V8 Transluminal BAV 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 (Part 21 CFR 801 Subpart C
CONTINUE ON A SEPARATE PAGE IF NEEDED	

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7. 510(K) SUMMARY

7.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: 3/31/15

7.1.1 Contact Information

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7.1.2 Device Information

Trade Name	V8 Transluminal BAV Catheter
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

7.2 PREDICATE DEVICE

The modified device is substantially equivalent to the InterValve V8 Transluminal BAV Catheter (K133607) and the Z-Med/Z-Med II (K122012).

7.3 DEVICE DESCRIPTION

The V8 Transluminal BAV Catheter System 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.

7.4 INTENDED USE

The V8 Transluminal BAV Catheter is intended to be used to dilate aortic valve tissue.

There is no change in intended use from the V8 predicate device.

7.5 INDICATIONS FOR USE

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

There is no change in the indications for use from the predicate devices.

7.6 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.

7.7 PERFORMANCE DATA

The performance testing performed during design verification and shelf life testing were not repeated because the design and materials of the device remain the same as the V8 predicate. Therefore there are no changes to the performance or safety of the predicate V8 device. The testing performed during the predicate design verification included:

- Balloon rated burst pressure
- Balloon compliance
- Critical dimension verifications
- Guidewire and introducer compatibility
- Deflation times
- Repeat inflation
- Leak
- Tensile
- Kink
- Torque

Additional bench testing for the use of the V8 as a post-dilatation balloon in a self-expanding TAVR included:

- The durability of the V8 when used in conjunction with a self-expanding TAVR
- The radial force exerted on a simulated annulus by a V8 and cylindrical balloon within a self-expanding TAVR

The proposed change to the V8 device labeling does not affect the requirements of the special controls because no design changes have been made to the predicate K133607 V8 device.

Table 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. 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. Shelf life testing was not repeated because there were no design changes to the predicate V8 device. 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.	Design verification testing was not repeated because there were no design changes made. Test data can be found in the K133607 submission. Additional bench testing was performed and is summarized in Section 11.5 of this submission.
In vivo evaluation of the device should demonstrate device	The shape of the device has not changed and the principles of operation are also the same. The

performance, including the ability of the device to treat aortic stenosis.	device dimensions are identical to the predicate device submitted in 510(k) notification K132728.
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.

7.8 SUBSTANTIAL EQUIVALENCE

The V8 device covered by this submission is substantially equivalent to the V8 predicate device (K133607) and the Z-Med predicate device (K122012). The device intended use has not changed and the overall design principles are the same. There has been no change to the general design or materials 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.

7.9 CONCLUSION

The modified V8 Transluminal BAV Catheter System is substantially equivalent to the predicate devices (K133607 and K122012) in design, materials, function and intended use.