

**K150343 V8 Transluminal BAV Catheter**Apr 3, 2015  
51 days to decisionK150343 · Product code: **OZT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k150343/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Feb 11, 2015
Decision date	Apr 3, 2015
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intervalve, Inc.</b>
Location	Minneapolis, MN, US
Contact	Mark Ungs
510(k) history	5 submissions · 5 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150343/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 3, 2026