

K152150 V8 Balloon Aortic Valvuloplasty CatheterDec 18, 2015
137 days to decisionK152150 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k152150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Aug 3, 2015
Decision date	Dec 18, 2015
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intervalve, Inc.
Location	Minneapolis, MN, US
Contact	Mark Unga
510(k) history	5 submissions · 5 cleared · 2013-2015

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