

K132728 V8 TRANSLUMINAL BAV CATHETERNov 22, 2013
80 days to decisionK132728 · Product code: **OZT** · Cardiovascular
Source: <https://www.510kdatabase.net/k132728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Sep 3, 2013
Decision date	Nov 22, 2013
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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