FDA 510(k) Premarket Notification

K150343 V8 Transluminal BAV Catheter

CLEARED

Apr 3, 2015
51 days to decision

K150343 · Product code: **OZT** · Cardiovascular
Source: https://www.510kdatabase.net/k150343/

SUBMISSION DETAILS

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

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