K121083 TRUE DILATATION PERCUTANEOUS TRANSLUMINAL VALVULOPLASTY CATHETER, 20MM X 4.5CM, TRUE DILATATION PERCUTANEOUS TRANSLUMINA

CLEARED

Oct 11, 2012
184 days to decision

K121083 · Product code: **OZT** · Cardiovascular
Source: https://www.510kdatabase.net/k121083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon Aortic Valvuloplasty (OZT)
Date received	Apr 10, 2012
Decision date	Oct 11, 2012
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Loma Vista Medical**
Location	Sunnyvale, CA, US
Contact	TIFFINI DIAGE
510(k) history	1 submissions · 1 cleared · 2012-2012