

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

Oct 11, 2012  
184 days to decision

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

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k121083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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