

**K153682 Chocolate XD PTCA Balloon Catheter**Jun 23, 2016  
184 days to decisionK153682 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153682/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 22, 2015
Decision date	Jun 23, 2016
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trireme Medical, LLC</b>
Location	Pleasanton, CA, US
Contact	Shiva Ardakani
510(k) history	2 submissions · 2 cleared · 2015-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153682/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 2, 2026