

**K121402 CHOCOLATE PTA BALLOON CATHETER (OVER THE WIRE) 0.014 GUIDE WIRE CHOCOLATE PTA BALLOON CATHETER (OVER THE WIRE) 0.018&apos; G**Jun 8, 2012  
29 days to decisionK121402 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k121402/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	May 10, 2012
Decision date	Jun 8, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trireme Medical, Inc.</b>
Location	Pleasanton, CA, US
Contact	SHIVA ARDAKANI
510(k) history	12 submissions · 12 cleared · 2010-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121402/> 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 6, 2026