

**K120677 CHOCOLATE PTA BALLON CATHETER (OVER THE WIRE) GUIDE WIRE (0.014)**

Mar 15, 2012  
9 days to decision

K120677 · Product code: LIT · Cardiovascular  
Source: <https://www.510kdatabase.net/k120677/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Mar 6, 2012
Decision date	Mar 15, 2012
Days to decision	9 days
Third-party review	Yes
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/k120677/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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