

**K103534 GLIDERXTREME PTA BALLOON CATHETER (CB)  
(OVER THE WIRE) 0.014 / 0.018 GUIDE WIRE**Jan 5, 2011  
35 days to decisionK103534 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k103534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 1, 2010
Decision date	Jan 5, 2011
Days to decision	35 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/k103534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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