

**K051670 RF TUNNELER WIRE**Mar 30, 2006  
281 days to decisionK051670 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k051670/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jun 22, 2005
Decision date	Mar 30, 2006
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baylis Medical Co., Inc.</b>
Location	Mississauga, CA
Contact	MEGHAL KHAKHAR
510(k) history	28 submissions · 28 cleared · 1998-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051670/> 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 May 19, 2026