

**K122926 SUREFLEX STEERABLE GUIDING SHEATH KIT**Jan 24, 2013  
122 days to decisionK122926 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122926/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Sep 24, 2012
Decision date	Jan 24, 2013
Days to decision	122 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/k122926/> 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