

**K231227 SureFlex HD Steerable Sheath, VersaCross HD Steerable Sheath**Dec 20, 2023  
236 days to decisionK231227 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 28, 2023
Decision date	Dec 20, 2023
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baylis Medical Company, Inc.</b>
Location	Mississauga, Ontario, CA
Contact	Shilpa Sharma
510(k) history	24 submissions · 24 cleared · 2012-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231227/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026