

**K190644 Guide Sheath**Apr 18, 2019  
36 days to decisionK190644 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190644/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 13, 2019
Decision date	Apr 18, 2019
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surmodics, Inc.</b>
Location	Eden Prairie, MN, US
Contact	Peggy Ju
510(k) history	11 submissions · 11 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190644/> 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 26, 2026