

**K242169 Morph DNA Steerable Introducer Sheath**Aug 23, 2024  
30 days to decisionK242169 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242169/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 24, 2024
Decision date	Aug 23, 2024
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biocardia</b>
Location	San Carlos, CA, US
Contact	Ed Gillis
510(k) history	2 submissions · 2 cleared · 2020-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242169/> 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 14, 2026