

**K161659 FlexSeal Introducer Sheath with Hydrophilic Coating**Jul 15, 2016  
29 days to decisionK161659 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161659/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 16, 2016
Decision date	Jul 15, 2016
Days to decision	29 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Libramedical, Inc.</b>
Location	Minneapolis, MN, US
Contact	SEW-WAH TAY
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161659/> 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 June 2, 2026