

**K163268 FlexCath Select Steerable Sheath and Dilator**Feb 2, 2017  
73 days to decisionK163268 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k163268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 21, 2016
Decision date	Feb 2, 2017
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Cryocath, LP</b>
Location	Kirkland, CA
Contact	Natalie Sadeghi
510(k) history	6 submissions · 6 cleared · 2010-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163268/> 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 20, 2026