

**K162097 InTRAKit**Nov 17, 2016  
111 days to decisionK162097 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162097/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 29, 2016
Decision date	Nov 17, 2016
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Vascular</b>
Location	Walker, MI, US
Contact	Nisarg Shah
510(k) history	475 submissions · 453 cleared · 1977-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162097/> 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 13, 2026