

**K182957 Heli-FX EndoAnchor System**Nov 21, 2018  
28 days to decisionK182957 · Product code: **OTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182957/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endovascular Suturing System (OTD)
Date received	Oct 24, 2018
Decision date	Nov 21, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Vascular, Inc.</b>
Location	Plymouth, MN, US
Contact	Janelle Wong Keller
510(k) history	5 submissions · 5 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182957/> 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 28, 2026