

**K182570 Venture 0.014 Catheter**

Mar 13, 2019  
176 days to decision

K182570 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182570/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 18, 2018
Decision date	Mar 13, 2019
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vascular Solutions, LLC</b>
Location	Maple Grove, MN, US
Contact	Becky Astrup
Website	<a href="http://vasc.com/">http://vasc.com/</a>
510(k) history	11 submissions · 11 cleared · 2019-2024

Vascular Solutions, LLC is an interventional medical device company now part of Teleflex. The company specializes in cardiovascular devices for coronary and peripheral interventions, structural heart procedures, and mechanical circulatory support. Vascular Solutions operates with a manufacturing facility in Maple Grove, Minnesota. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2019. Cardiovascular devices represent 91% of its regulatory submissions. The latest clearance was in 2024, demonstrating continued product innova...

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