

**K180919 GORE Tri-Lumen Catheter**Oct 5, 2018  
179 days to decisionK180919 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180919/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 9, 2018
Decision date	Oct 5, 2018
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W. L. Gore and Associates, Inc.</b>
Location	Phoenix, AZ, US
Contact	Michael Ivey
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
510(k) history	3 submissions · 3 cleared · 2018-2022

W. L. Gore and Associates, Inc. is a medical device manufacturer with a manufacturing facility in Phoenix, US. The company specializes in cardiovascular and surgical devices. The company has received FDA 510(k) clearances from total submissions between 2018 and 2022. Its cleared devices focus primarily on cardiovascular applications, including catheter systems and biomaterials for general and plastic surgery. This regulatory record reflects the company's historical activity in the medical device sector. Notable cleared devices include catheter systems designed for cardiov...

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