

**K183357 XableCath Crossing Catheter**Jan 21, 2019  
48 days to decisionK183357 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k183357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Dec 4, 2018
Decision date	Jan 21, 2019
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Xablecath, Inc.</b>
Location	Salt Lake City, UT, US
Contact	Rick Gaykowski
510(k) history	3 submissions · 3 cleared · 2017-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183357/> 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