

**K232562 PowerWire Radiofrequency Guidewire Kit**Feb 28, 2024  
188 days to decisionK232562 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k232562/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 24, 2023
Decision date	Feb 28, 2024
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baylis Medical Technologies, Inc.</b>
Location	Mississauga, CA
Contact	Stephanie Gallone
510(k) history	5 submissions · 3 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232562/> 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