

K251158 PowerWire® 14 Radiofrequency Guidewire KitSep 11, 2025
149 days to decisionK251158 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k251158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Apr 15, 2025
Decision date	Sep 11, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baylis Medical Technologies, Inc.
Location	Mississauga, CA
Contact	Barb Boyce
510(k) history	5 submissions · 3 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251158/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026