

**K242824 PTFE Guidewire**Dec 6, 2024  
79 days to decisionK242824 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k242824/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 18, 2024
Decision date	Dec 6, 2024
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lake Region Medical</b>
Location	Chaska, MN, US
Contact	Clara Lee
510(k) history	16 submissions · 16 cleared · 2008-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242824/> 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