

**K221575 Pre-Formed Blue**Oct 7, 2022  
128 days to decisionK221575 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k221575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jun 1, 2022
Decision date	Oct 7, 2022
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lake Region Medical</b>
Location	Chaska, MN, US
Contact	Deko Hussein
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/k221575/> 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 14, 2026