

**K221351 Mechanical Guidewire**Dec 19, 2022  
223 days to decisionK221351 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k221351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 10, 2022
Decision date	Dec 19, 2022
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baylis Medical Company, Inc.</b>
Location	Mississauga, Ontario, CA
Contact	May Tsai
510(k) history	24 submissions · 24 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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