

**K253746 Enroute 0.014&apos;&apos; Transcarotid Guidewire**

Mar 19, 2026  
114 days to decision

K253746 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253746/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 25, 2025
Decision date	Mar 19, 2026
Days to decision	114 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	Amy Carter
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/k253746/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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