FDA 510(k) Premarket Notification

K253746 Enroute 0.014'' Transcarotid Guidewire

CLEARED

Mar 19, 2026
114 days to decision

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

SUBMISSION DETAILS

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

Company	**Lake Region Medical**
Location	Chaska, MN, US
Contact	Amy Carter
510(k) history	16 submissions · 16 cleared · 2008-2026