

K160643 ENROUTE 0.014 GuidewireOct 18, 2016
225 days to decisionK160643 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k160643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 7, 2016
Decision date	Oct 18, 2016
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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