

**K151244 Pre-Formed Guidewire**Jun 11, 2015  
31 days to decisionK151244 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k151244/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	May 11, 2015
Decision date	Jun 11, 2015
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Lake Region Medical</b>
Location	Chaska, MN, US
Contact	Mathew Pexa
510(k) history	16 submissions · 16 cleared · 2008-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151244/> 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