

**K850828 WIRE, GUIDE - MODIFICATION**Jun 26, 1985  
121 days to decisionK850828 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k850828/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 25, 1985
Decision date	Jun 26, 1985
Days to decision	121 days
Third-party review	No

**APPLICANT**

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Company	<b>Lake Region Mfg., Inc.</b>
Location	Mchenry, IL, US
Contact	JIM KLOSTERMAN
510(k) history	42 submissions · 42 cleared · 1977-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850828/>; 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 22, 2026