

K080144 MANDREL GUIDEWIRES OR M-WIRESFeb 26, 2008
35 days to decisionK080144 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k080144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 22, 2008
Decision date	Feb 26, 2008
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lake Region Mfg., Inc.
Location	Mchenry, IL, US
Contact	DEEP PAL
510(k) history	42 submissions · 42 cleared · 1977-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080144/> Data sourced from FDA 510(k) public records (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. - Generated May 22, 2026