

K000011 MODIFIED HYDROPHILIC COATED GUIDEWIREMar 1, 2000
58 days to decisionK000011 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k000011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 3, 2000
Decision date	Mar 1, 2000
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000011/> 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