

K053187 AMPLATZER NOODLEWIRE GUIDEWIREApr 27, 2006
163 days to decisionK053187 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k053187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Nov 15, 2005
Decision date	Apr 27, 2006
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aga Medical Corp.
Location	Plymouth, MN, US
Contact	PATRICIA A LAFORET
510(k) history	14 submissions · 14 cleared · 2000-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k053187/> 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 June 14, 2026