

K090970 FLOCONTROL , MODEL 1028Jun 12, 2009
67 days to decisionK090970 · Product code: **MJN** · Cardiovascular
Source: <https://www.510kdatabase.net/k090970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Apr 6, 2009
Decision date	Jun 12, 2009
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coaxia, Inc.
Location	Maple Grove, MN, US
Contact	SHARON D KVISTAD
510(k) history	2 submissions · 2 cleared · 2003-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090970/> 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 22, 2026