

K051580 VP SHEATHOct 31, 2005
138 days to decisionK051580 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k051580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 15, 2005
Decision date	Oct 31, 2005
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Flowcardia, Inc.
Location	Sunnyvale, CA, US
Contact	RICHARD SPANO
510(k) history	11 submissions · 11 cleared · 2005-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k051580/> 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 21, 2026