

**K042541 MODIFICATION TO POLARCATH PERIPHERAL
DILATATION SYSTEM**Oct 12, 2004
22 days to decisionK042541 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k042541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 20, 2004
Decision date	Oct 12, 2004
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryo Vascular Systems, Inc.
Location	Lost Gatos, CA, US
Contact	KIM TOMPKINS
510(k) history	7 submissions · 7 cleared · 2002-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042541/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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