

K062877 TWIN-PASS .023 DUAL ACCESS CATHETER, MODEL 5230Jan 18, 2007
114 days to decisionK062877 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k062877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 26, 2006
Decision date	Jan 18, 2007
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	JULIE TAPPER
Website	http://vasc.com/
510(k) history	103 submissions · 102 cleared · 2002-2018

Vascular Solutions, Inc. specialized in cardiovascular interventional devices with a manufacturing facility in Minneapolis, US. The company developed a broad portfolio of catheters, guidewires, and vascular access systems for interventional cardiology and radiology procedures. The company received FDA 510(k) clearances from total submissions between 2002 and 2018. All submissions in the regulatory record were cleared. Cardiovascular devices dominated the company's portfolio, including mechanical thrombectomy systems, aspiration systems, guidewires, and vascular closure te...

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Device record: <https://www.510kdatabase.net/k062877/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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