

**K042937 MODIFICATION TO VASCULAR SOLUTIONS PRONTO
EXTRACTION CATHETER**Jan 31, 2005
98 days to decisionK042937 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k042937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Oct 25, 2004
Decision date	Jan 31, 2005
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	DEBORAH L NEYMARK
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/k042937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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