

**K083784 PRONTO V3 EXTRACTION CENTER, MODEL 5003,
PRONTO LP EXTRACTION CATHETER, MODEL 5010, SKYWAY
RX SUPPORT CATHETER,**Mar 30, 2009
101 days to decisionK083784 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k083784/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Dec 19, 2008
Decision date	Mar 30, 2009
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	CHARMAINE SUTTON
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...