

K103405 PRONTO V4 EXTRACTION CATHETER 5.5FDec 22, 2010
33 days to decisionK103405 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k103405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Nov 19, 2010
Decision date	Dec 22, 2010
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary
Other names	PRONTO V4 EXTRACTION CATHETER 6F; PRONTO V4 EXTRACTION 7F; PRONTO V4 EXTRACTION CATH

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	MATT NIENSTEDT
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...
