FDA 510(k) Premarket Notification

CLEARED

K052232 VASCULAR SOLUTIONS PRONTO V3 EXTRACTION CATHETER

Sep 28, 2005
42 days to decision

K052232 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k052232/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Aug 17, 2005
Decision date	Sep 28, 2005
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions, Inc.**
Location	Minneapolis, MN, US
Contact	SARA L COON
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...