

**K012293 VASCULAR SOLUTIONS DUETT FLOWABLE
HEMOSTAT**Jan 18, 2002
182 days to decisionK012293 · Product code: **QSX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k012293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (QSX)
Date received	Jul 20, 2001
Decision date	Jan 18, 2002
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	DEBORAH L JENSEN
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...