

K030836 D-STAT-DRY HEMOSTATIC BANDAGESep 17, 2003
184 days to decisionK030836 · Product code: **Q SX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k030836/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (Q SX)
Date received	Mar 17, 2003
Decision date	Sep 17, 2003
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary
Other names	D-STAT RADIAL HEMOSTATIC BANDAGE

APPLICANT

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