

**K050133 D-STAT RADIAL HEMOSTATIC BAND**Feb 18, 2005  
28 days to decisionK050133 · Product code: **QSX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k050133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (QSX)
Date received	Jan 21, 2005
Decision date	Feb 18, 2005
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vascular Solutions, Inc.</b>
Location	Minneapolis, MN, US
Contact	LINDA BUSKLEIN
Website	<a href="http://vasc.com/">http://vasc.com/</a>
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...

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