

K092612 D-STAT RAD-BAND, RAD-BAND, MODELS 3501, 3505Sep 11, 2009
16 days to decisionK092612 · Product code: **QSX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k092612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (QSX)
Date received	Aug 26, 2009
Decision date	Sep 11, 2009
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, Inc.
Location	Minneapolis, MN, US
Contact	LISA GALLATIN
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...
