

**K143038 Gel-Block 10X embolization pledgets**Nov 20, 2014  
29 days to decisionK143038 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k143038/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 22, 2014
Decision date	Nov 20, 2014
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vascular Solutions, Inc.</b>
Location	Minneapolis, MN, US
Contact	ADAM E TTL
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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