

**K063860 THROMBIGEL THROMBIN/GELATIN FOAM  
HEMOSTAT**Feb 13, 2007  
47 days to decisionK063860 · Product code: **QSX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k063860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (QSX)
Date received	Dec 28, 2006
Decision date	Feb 13, 2007
Days to decision	47 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vascular Solutions, Inc.</b>
Location	Minneapolis, MN, US
Contact	JAMES CHAPMAN
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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Device record: <https://www.510kdatabase.net/k063860/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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