

**K053644 THROMBIGEL THROMBIN/GELATIN FOAM
HEMOSTAT**Feb 9, 2006
41 days to decisionK053644 · Product code: **QSX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k053644/>**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 30, 2005 |
| Decision date | Feb 9, 2006 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Vascular Solutions, Inc. |
| Location | Minneapolis, MN, US |
| Contact | LINDA BUSKLEIN |
| 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...