

**K033721 VASCULAR SOLUTIONS AUTO-FILL SYRINGE KIT**Feb 13, 2004  
79 days to decisionK033721 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k033721/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 26, 2003
Decision date	Feb 13, 2004
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Vascular Solutions, Inc.</b>
Location	Minneapolis, MN, US
Contact	SARA L COON
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...

---