

K171946 Gel-BeadOct 25, 2017
118 days to decisionK171946 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k171946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 29, 2017
Decision date	Oct 25, 2017
Days to decision	118 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...
