FDA 510(k) Premarket Notification

K133237 GEL-BEAD EMBOLIZATION SPHERES

CLEARED

Apr 25, 2014
186 days to decision

K133237 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k133237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Oct 21, 2013
Decision date	Apr 25, 2014
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions, Inc.**
Location	Minneapolis, MN, US
Contact	ELLIE GILLESPIE
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...