FDA 510(k) Premarket Notification

K163444 Spectre guidewire

CLEARED

Jan 6, 2017
29 days to decision

K163444 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k163444/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 8, 2016
Decision date	Jan 6, 2017
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions, Inc.**
Location	Minneapolis, MN, US
Contact	Beka Vite
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...