FDA 510(k) Premarket Notification

K172090 GuideLiner V3 Catheter

CLEARED

Oct 20, 2017
101 days to decision

K172090 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k172090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 11, 2017
Decision date	Oct 20, 2017
Days to decision	101 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...