CLEARED

K212167 R350 guidewire, Spectre guidewire, Raider guidewire, Bandit guidewire, Warrior guidewire

Feb 9, 2022
212 days to decision

K212167 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k212167/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 12, 2021
Decision date	Feb 9, 2022
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions, LLC**
Location	Maple Grove, MN, US
Contact	Beka Vite
Website	http://vasc.com/
510(k) history	11 submissions · 11 cleared · 2019-2024

Vascular Solutions, LLC is an interventional medical device company now part of Teleflex. The company specializes in cardiovascular devices for coronary and peripheral interventions, structural heart procedures, and mechanical circulatory support. Vascular Solutions operates with a manufacturing facility in Maple Grove, Minnesota. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2019. Cardiovascular devices represent 91% of its regulatory submissions. The latest clearance was in 2024, demonstrating continued product innova...

CLINICAL EVIDENCE - NCT03988166

Chronic Total Occlusion Percutaneous Coronary Intervention Study

Status	Completed
Enrollment	150 patients (actual)
Study sites	13 sites
Condition studied	Chronic Total Occlusion; Ischemic Heart Disease; Chronic Total Occlusion of Coronary Artery
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Feb 22, 2021
Sponsor	Vascular Solutions LLC (Industry)

Primary outcome

Number of Participants With Procedure Success

Secondary outcome

Number of Participants With Successful Recanalization.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03988166