FDA 510(k) Premarket Notification

K192454 Wattson Temporary Pacing Guidewire

CLEARED

Jan 15, 2020
128 days to decision

K192454 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k192454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Sep 9, 2019
Decision date	Jan 15, 2020
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vascular Solutions**
Location	Maple Grove, MN, US
Contact	Nancy Frame
Website	http://vasc.com/
510(k) history	1 submissions · 1 cleared · 2020-2020

Vascular Solutions specializes in Cardiovascular devices for interventional procedures. The company operates with a manufacturing facility in Maple Grove, US. Now part of Teleflex, the brand continues to operate under the parent company's interventional portfolio. The company has received FDA 510(k) clearance from total submission. All regulatory activity occurred in 2020, reflecting the company's historical record in the Cardiovascular device space. The cleared device, Wattson Temporary Pacing Guidewire, represents the company's focus on specialized interventional techno...

CLINICAL EVIDENCE - NCT03748316

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - *No results published to ClinicalTrials.gov*
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03748316