

K230637 Wattson temporary pacing guidewire (2250)May 5, 2023
59 days to decisionK230637 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k230637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 7, 2023
Decision date	May 5, 2023
Days to decision	59 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	Vite Beka
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...