

K193119 Twin-Pass Dual Access CatheterJun 29, 2020
230 days to decisionK193119 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k193119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 12, 2019
Decision date	Jun 29, 2020
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, LLC
Location	Maple Grove, MN, US
Contact	Iroquois Ledbeter
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193119/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026