

K212725 ViperCross Support CathetersSep 24, 2021
28 days to decisionK212725 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k212725/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 27, 2021
Decision date	Sep 24, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Systems, Inc.
Location	Saint Paul, MN, US
Contact	Erika Huffman
510(k) history	26 submissions · 26 cleared · 2007-2022

REGULATORY CONSULTANT

Consulting firm	Biomerics
Contact	Jonathan Holmes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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