

K180201 Route 92 Medical Access SystemMay 23, 2018
119 days to decisionK180201 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k180201/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 24, 2018
Decision date	May 23, 2018
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Route 92 Medical, Inc.
Location	San Mateo, CA, US
Contact	Kirsten Valley
510(k) history	13 submissions · 13 cleared · 2018-2025

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