

K203043 Route 92 Medical 070 Access SystemNov 11, 2020
36 days to decisionK203043 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k203043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Oct 6, 2020
Decision date	Nov 11, 2020
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203043/> 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 26, 2026