

K240529 8F Modified Sheath SystemOct 2, 2024
222 days to decisionK240529 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k240529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Feb 23, 2024
Decision date	Oct 2, 2024
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	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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