

**K231583 Route 92 Medical Full Length 054 Access System**Aug 15, 2023  
76 days to decisionK231583 · Product code: **QJP** · Neurology  
Source: <https://www.510kdatabase.net/k231583/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Special  |
| Device classification | Catheter, Percutaneous, Neurovasculature (QJP) |
| Date received         | May 31, 2023                                   |
| Decision date         | Aug 15, 2023                                   |
| Days to decision      | 76 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231583/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026