

K254223 Next Generation 088 CatheterApr 16, 2026
108 days to decisionK254223 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k254223/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Dec 29, 2025
Decision date	Apr 16, 2026
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Balt USA, LLC
Location	Irvine, CA, US
Contact	Subha Elango
510(k) history	18 submissions · 18 cleared · 2018-2026

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