

K234074 Next Generation Access CatheterJul 2, 2024
193 days to decisionK234074 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k234074/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Dec 22, 2023
Decision date	Jul 2, 2024
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234074/> 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 13, 2026