

K253359 Zenith Distal Access Long SheathMay 22, 2026
234 days to decisionK253359 · Product code: **QJP** · Neurology
Source: <https://www.510kdatabase.net/k253359/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous, Neurovasculature (QJP)
Date received	Sep 30, 2025
Decision date	May 22, 2026
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Zenith Vascular SciTech Limited
Location	Suzhou, CN
Contact	Yexia Zhang
510(k) history	4 submissions · 4 cleared · 2025-2026

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