

K243534 Micro CatheterJul 30, 2025
257 days to decisionK243534 · Product code: **KRA** · Neurology
Source: <https://www.510kdatabase.net/k243534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Nov 15, 2024
Decision date	Jul 30, 2025
Days to decision	257 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	Xia Jie
510(k) history	2 submissions · 2 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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