

**K252317 Zenith Micro Guidewire**Apr 16, 2026  
265 days to decisionK252317 · Product code: **MOF** · Neurology  
Source: <https://www.510kdatabase.net/k252317/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Jul 25, 2025
Decision date	Apr 16, 2026
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Zenith Vascular SciTech Limited</b>
Location	Suzhou, CN
Contact	Yexia Zhang
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252317/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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