

**K250132 Ureteral Access Sheath**Sep 5, 2025  
231 days to decisionK250132 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 17, 2025
Decision date	Sep 5, 2025
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Yigao Medical Technology Co., Ltd.</b>
Location	Hangzhou, CN
Contact	Serena Zhou
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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