

K251599 Single-use Ureteral Access SheathJul 3, 2025
37 days to decisionK251599 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	May 27, 2025
Decision date	Jul 3, 2025
Days to decision	37 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Vathin Medical Instrument Co., Ltd.
Location	Xiangtan, CN
Contact	Ya Tang
510(k) history	17 submissions · 17 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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