

K240167 Single-use Ureteral Access SheathOct 8, 2024
260 days to decisionK240167 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k240167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 22, 2024
Decision date	Oct 8, 2024
Days to decision	260 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	Jing Du
510(k) history	17 submissions · 17 cleared · 2020-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240167/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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