

K243025 Ureteral Access SheathJan 30, 2025
125 days to decisionK243025 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Sep 27, 2024
Decision date	Jan 30, 2025
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Seplou (Zhuhai) Co., Ltd.
Location	Zhuhai, CN
Contact	Vince Zeng
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243025/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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