

K243710 Disposable ureteral access sheathApr 11, 2025
130 days to decisionK243710 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Dec 2, 2024
Decision date	Apr 11, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Trious Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Yingfang Yi
510(k) history	3 submissions · 3 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Kyra Kang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243710/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026