FDA 510(k) Premarket Notification

CLEARED

K243830 Disposable ureteral stent

May 14, 2025
152 days to decision

K243830 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k243830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	Dec 13, 2024
Decision date	May 14, 2025
Days to decision	152 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.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov