FDA 510(k) Premarket Notification

CLEARED

K250448 Disposable Percutaneous Nephrostomy Dilatation Kit

Jul 3, 2025
135 days to decision

K250448 · Product code: **LJE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250448/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Feb 18, 2025
Decision date	Jul 3, 2025
Days to decision	135 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	Yi Yingfang
510(k) history	3 submissions · 3 cleared · 2025-2025

REGULATORY CONSULTANT

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

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov