FDA 510(k) Premarket Notification

K241181 Disposable Ureteral Guide Sheath

CLEARED

Aug 2, 2024
95 days to decision

K241181 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Apr 29, 2024
Decision date	Aug 2, 2024
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dongguan Zsr Biomedical Technology Company Limited**
Location	Dongguan, CN
Contact	Sharon Wen
510(k) history	2 submissions · 2 cleared · 2024-2025

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