FDA 510(k) Premarket Notification

CLEARED

K250128 Single Use Suction-Evacuation Ureteral Access Sheath

Sep 19, 2025
245 days to decision

K250128 · Product code: **FED** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 17, 2025
Decision date	Sep 19, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anhui Happiness Workshop Medical Instruments Co., Ltd.**
Location	Bengbu, CN
Contact	Shuanghong Wang
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Pure Global**
Contact	Jarvis Wu

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