

K241956 Single-Use Digital Flexible Ureteroscope (PUR12-1, PUR12-2, PUR12-3, PUR12-4, PUR12-5, PUR12-6, PUR12-S, PUR12-S1, PUR12-S2)Jan 22, 2025
203 days to decisionK241956 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jul 3, 2024
Decision date	Jan 22, 2025
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Endoso Life Technology Co., Ltd.
Location	Xiangtan, CN
Contact	Fu Wang
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Eric Zhang

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/k241956/> 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 14, 2026