

K243155 Single-Use Digital Flexible Ureteroscope(F-URS) (ZSR-URS-01, ZSR-URS-02, ZSR-URS-03, ZSR-URS-04)Feb 11, 2025
134 days to decisionK243155 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 30, 2024
Decision date	Feb 11, 2025
Days to decision	134 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	Wen Sharon
510(k) history	2 submissions · 2 cleared · 2024-2025

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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243155/> 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 13, 2026