

K252468 Single-use Digital Flexible Ureteroscope (GY-UR9.3)Dec 16, 2025
132 days to decisionK252468 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Aug 6, 2025
Decision date	Dec 16, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Single-use Digital Flexible Ureteroscope (GY-UR8.4); Single-use Digital Flexible Ureteroscope (GY-UR7.5); Endoscope camera system (GY-AIO-121)

APPLICANT

Company	Zhejiang Geyi Medical Instrument Co., Ltd.
Location	Jiande City, CN
Contact	Cathy Tan
510(k) history	1 submissions · 1 cleared · 2025-2025

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