

**K250049 Medical Video Endoscope [Standard Deflection]
(URS3005)**Aug 26, 2025
228 days to decisionK250049 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jan 10, 2025
Decision date	Aug 26, 2025
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Medical Video Endoscope [Reverse Deflection] (URS3005E); Medical Video Endoscope [Standard Deflection] (URS3006); Medical Video Endoscope [Reverse Deflection] (URS3006E); Medical Video Endoscope [Standard Deflection] (URS3016); Medical Video Endoscope [Reverse Deflection] (URS3016E); Image processor (DIS8000)

APPLICANT

Company	Seplou (Zhuhai) Co., Ltd.
Location	Zhuhai, CN
Contact	QingFu Zeng
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Chonconn Consulting Co., Ltd.
Contact	Jie Yang

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