

K243894 F88 URE-SD/RD Flexible UreteroscopeMay 2, 2025
135 days to decisionK243894 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscopy And Accessories, Flexible/rigid (FGB)
Date received	Dec 18, 2024
Decision date	May 2, 2025
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sg Endoscopy Pte, Ltd.
Location	N/A, SG
Contact	John Yeng Jie Woo
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Eliquent Life Sciences
Contact	Samantha Eakes

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

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