

K233372 KARL STORZ Fiber Telescopes for UrologyJul 25, 2024
297 days to decisionK233372 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k233372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Oct 2, 2023
Decision date	Jul 25, 2024
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Karl Storz SE & CO. KG
Location	Tuttlingen, DE
Contact	Alita McElroy
Website	https://www.karlstorz.com
510(k) history	23 submissions · 23 cleared · 2018-2026

Karl Storz SE & CO. KG is a medical device manufacturer headquartered in Tuttlingen, Germany. The company specializes in endoscopic instruments and visualization systems for surgical and diagnostic procedures. The company has received FDA 510(k) clearances from total submissions since 2018. Karl Storz devices span multiple surgical specialties, with particular strength in Gastroenterology & Urology applications. The latest FDA 510(k) clearance was granted in 2026, confirming the company's active regulatory engagement. Recent cleared devices include flexible video endoscop...

REGULATORY CONSULTANT

Consulting firm	Karl Storz Endoscopy America
Contact	Jordan Lydia Verla

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

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Device record: <https://www.510kdatabase.net/k233372/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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