

**K243550 KARL STORZ Flexible Video-Uretero-Renoscope (FLEX XC)**Jun 6, 2025  
203 days to decisionK243550 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Nov 15, 2024
Decision date	Jun 6, 2025
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Karl Storz SE &amp; CO. KG</b>
Location	Tuttlingen, DE
Contact	Emily Rhiel
Website	<a href="https://www.karlstorz.com">https://www.karlstorz.com</a>
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...