

K250388 ENDOFLATOR +Sep 22, 2025
223 days to decisionK250388 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Feb 11, 2025
Decision date	Sep 22, 2025
Days to decision	223 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	Emily Rhiel
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...

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Device record: <https://www.510kdatabase.net/k250388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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