FDA 510(k) Premarket Notification

CLEARED

K250927 KARL STORZ Cholangiography Set

Nov 22, 2025
239 days to decision

K250927 · Product code: **GCJ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250927/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Mar 28, 2025
Decision date	Nov 22, 2025
Days to decision	239 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	Jordan Lydia Verla
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