

K254228 KARL STORZ Trocars with Valve SealsMay 11, 2026
136 days to decisionK254228 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k254228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Dec 26, 2025
Decision date	May 11, 2026
Days to decision	136 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	Mario Trujillo
Website	https://www.karlstorz.com
510(k) history	24 submissions · 24 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...