FDA 510(k) Premarket Notification

K232486 KARL STORZ Monopolar Resectoscopes with HF Cable

CLEARED

May 7, 2024
265 days to decision

K232486 · Product code: **FJL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232486/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resectoscope (FJL)
Date received	Aug 16, 2023
Decision date	May 7, 2024
Days to decision	265 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	Leigh Spotten
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, Inc.**
Contact	Mario Trujillo

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k232486/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026