FDA 510(k) Premarket Notification

# K230535 KARL STORZ Urological Laser Accessories

**CLEARED**

Sep 8, 2023
193 days to decision

K230535 · Product code: **GEX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k230535/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Feb 27, 2023 |
| Decision date | Sep 8, 2023 |
| Days to decision | 193 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 | Alita McElroy |
| 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

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|---|---|
| Consulting firm | **Karl Storz Endoscopy America, Inc.** |
| Contact | Emily Rhiel |

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