FDA 510(k) Premarket Notification

CLEARED

K252800 KARL STORZ Endoscopic Accessories for Urology

Jun 3, 2026
273 days to decision

K252800 · Product code: **OCZ** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Grasping/cutting Instrument, Non-powered (OCZ)
Date received	Sep 3, 2025
Decision date	Jun 3, 2026
Days to decision	273 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	Jennifer Downing
Website	https://www.karlstorz.com
510(k) history	25 submissions · 25 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...