FDA 510(k) Premarket Notification

CLEARED

K241945 KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278AC2)

Aug 1, 2024
29 days to decision

K241945 · Product code: **FGB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241945/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jul 3, 2024
Decision date	Aug 1, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278ACU1)

APPLICANT

Company	**Karl Storz SE & CO. KG**
Location	Tuttlingen, DE
Contact	Thomas Ostrowski
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...