

K212476 KARL STORZ Flexible HD Cysto-Urethroscope SystemSep 3, 2021
28 days to decisionK212476 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k212476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Aug 6, 2021
Decision date	Sep 3, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	KARL STORZ Endoscopy-America, Inc.
Location	Mchenry, IL, US
Contact	Winkie Wong
510(k) history	361 submissions · 361 cleared · 1980-2024

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