

K191357 Flexible HD Cysto-Urethroscope SystemSep 18, 2019
120 days to decisionK191357 · Product code: **FAJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	May 21, 2019
Decision date	Sep 18, 2019
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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