

**K182723 Flexible HD Cysto-Urethroscope System**Apr 23, 2019  
207 days to decisionK182723 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k182723/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Sep 28, 2018
Decision date	Apr 23, 2019
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KARL STORZ Endoscopy-America, Inc.</b>
Location	Mchenry, IL, US
Contact	Nozomi Yagi
510(k) history	361 submissions · 361 cleared · 1980-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182723/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026