

**K082046 KARL STORZ PEDIATRIC FLEXIBLE CYSTO-  
URETHRO-FIBERSCOPE, MODEL 11278C1/ACUI AND CIRCON  
AUR-735 PEDIATRIC CYSTOURETHEROSCO**Oct 10, 2008  
84 days to decisionK082046 · Product code: **FBO** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082046/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystourethroscope (FBO)
Date received	Jul 18, 2008
Decision date	Oct 10, 2008
Days to decision	84 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	MONIKA CAMPBELL
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/k082046/> 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 15, 2026