

**K030960 ECN ELECTRONIC VIDEO CYSTONEPHROSCOPE**Jul 16, 2003  
111 days to decisionK030960 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k030960/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Mar 27, 2003
Decision date	Jul 16, 2003
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acmi Corporation</b>
Location	Southborough, MA, US
Contact	John DeLucia
510(k) history	16 submissions · 16 cleared · 2002-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030960/> 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 June 29, 2026