

**K042225 ACMI INVISIO ICN, MODELS ICN-0564 AND ICN-0565**Sep 10, 2004  
24 days to decisionK042225 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k042225/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Aug 17, 2004
Decision date	Sep 10, 2004
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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