

**K090814 MODIFICATION TO GYRUS ACFI INVISIO ICN,  
MODELS ICN-0564 AND ICN-0565**Apr 20, 2009  
26 days to decisionK090814 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k090814/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Mar 25, 2009
Decision date	Apr 20, 2009
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gyrus Acmi, Inc.</b>
Location	Westborough, MA, US
Contact	GRAHAM A.L. BAILLIE
Website	<a href="https://www.olympusmedical.com">https://www.olympusmedical.com</a>
510(k) history	42 submissions · 42 cleared · 2007-2026

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