

**K881004 OLYMPUS-KEYMED ENDOSCOPIC CO2 REGULATOR,  
MODEL ECR**May 12, 1988  
64 days to decisionK881004 · Product code: **FCX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k881004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Mar 9, 1988
Decision date	May 12, 1988
Days to decision	64 days
Third-party review	No

**APPLICANT**

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Company	<b>Keymed, Inc.</b>
Location	Mchenry, IL, US
Contact	ROGER GRAY
510(k) history	29 submissions · 29 cleared · 1981-2010

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881004/>; 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 21, 2026