

**K133976 FUJIFILM ENDOSCOPIC CO2 REGULATOR**Sep 9, 2014  
257 days to decisionK133976 · Product code: **FCX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k133976/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Dec 26, 2013
Decision date	Sep 9, 2014
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujifilm Medical System U.S.A., Inc.</b>
Location	Stamford, CT, US
Contact	GINA WALLJASPER
510(k) history	71 submissions · 71 cleared · 1988-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133976/> 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 16, 2026