

**K900016 TRANS/R - FP(3)**Jun 11, 1990  
160 days to decisionK900016 · Product code: **FCY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k900016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bulb, Inflation, For Endoscope (FCY)
Date received	Jan 2, 1990
Decision date	Jun 11, 1990
Days to decision	160 days
Third-party review	No

**APPLICANT**

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Company	<b>CIVCO Medical Instruments Co., Inc.</b>
Location	Walker, MI, US
Contact	J WEDEL
510(k) history	29 submissions · 29 cleared · 1982-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k900016/>; 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 17, 2026