

**K884379 MAGLINTE ENTEROCLYSIS CATHETER**Feb 28, 1989  
133 days to decisionK884379 · Product code: **FGD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k884379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention, Barium Enema With Bag (FGD)
Date received	Oct 18, 1988
Decision date	Feb 28, 1989
Days to decision	133 days
Third-party review	No

**APPLICANT**

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Company	<b>Lafayette Pharmacal, Inc.</b>
Location	Lafayette, IN, US
Contact	ROBERT A SHARP
510(k) history	4 submissions · 3 cleared · 1986-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884379/>; 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 20, 2026