

**K853683 UMS-100**Jan 10, 1986  
128 days to decisionK853683 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k853683/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP)
Date received	Sep 4, 1985
Decision date	Jan 10, 1986
Days to decision	128 days
Third-party review	No

**APPLICANT**

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Company	<b>Narco Bio-Systems</b>
Location	Mchenry, IL, US
Contact	HARVEY KNAUSS
510(k) history	9 submissions · 9 cleared · 1976-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853683/>; 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 22, 2026