

**K912451 URODYNAMIC RECTAL BALLOON**Dec 2, 1991  
182 days to decisionK912451 · Product code: **FAP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k912451/>**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	Jun 3, 1991
Decision date	Dec 2, 1991
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cook Urological, Inc.</b>
Location	Spencer, IN, US
Contact	MICHELLE YOUNG
510(k) history	104 submissions · 102 cleared · 1986-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912451/> 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 June 19, 2026