

**K954315 PVC ABDOMINAL/RECTAL PRESSURE CATHETER**Nov 30, 1995  
76 days to decisionK954315 · Product code: **FEN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k954315/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Sep 15, 1995
Decision date	Nov 30, 1995
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Life-Tech Intl., Inc.</b>
Location	Walker, MI, US
Contact	ALFRED C COATS
510(k) history	68 submissions · 66 cleared · 1982-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954315/> 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 21, 2026