

**K953353 UROVISION JANUS**Sep 8, 1995  
53 days to decisionK953353 · Product code: **FEN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k953353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Jul 17, 1995
Decision date	Sep 8, 1995
Days to decision	53 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953353/> 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