

**K082701 URONIRS, MODEL 2000**Dec 18, 2008  
93 days to decisionK082701 · Product code: **FEN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082701/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Cystometric, Hydraulic (FEN)
Date received	Sep 16, 2008
Decision date	Dec 18, 2008
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Urodynamix Technologies, Ltd.</b>
Location	Vancouver Bc, CA
Contact	ANDRE KINDSVATER
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082701/> 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 24, 2026