

**K920451 ENDOTEK ULTRA SYSTEM**Sep 17, 1992  
226 days to decisionK920451 · Product code: **FAP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k920451/>**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	Feb 4, 1992
Decision date	Sep 17, 1992
Days to decision	226 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Surgitek</b>
Location	Mchenry, IL, US
Contact	WILLIAM H DUFFELL
510(k) history	29 submissions · 28 cleared · 1983-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920451/> 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 27, 2026