

**K851684 UROTEC/FRANKLIN SOFT SIMPLASTIC CATHETER**Jul 2, 1985  
70 days to decisionK851684 · Product code: **KOD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k851684/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Apr 23, 1985
Decision date	Jul 2, 1985
Days to decision	70 days
Third-party review	No

**APPLICANT**

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Company	<b>Urotec Systems Corp.</b>
Location	Pittsburgh, PA, US
Contact	SUNIL WADHWANI
510(k) history	2 submissions · 2 cleared · 1985-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851684/>; 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 July 3, 2026