

**K051905 UROPLASTY RIGID ENDOSCOPIC NEEDLE**Aug 29, 2005  
46 days to decisionK051905 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k051905/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                          |
| Submission type       | Traditional   |
| Device classification | Endoscopic Injection Needle, Gastroenterology-urology (FBK) |
| Date received         | Jul 14, 2005  |
| Decision date         | Aug 29, 2005  |
| Days to decision      | 46 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Uroplasty, Inc.</b>                |
| Location       | Minneapolis, MN, US                   |
| Contact        | MICHAEL MORRELL                       |
| 510(k) history | 8 submissions · 8 cleared · 2005-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051905/> 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 14, 2026