

**K130441 FALLER STYLET**Apr 19, 2013  
57 days to decisionK130441 · Product code: **FJS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k130441/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peritoneal, Long-term Indwelling (FJS)
Date received	Feb 21, 2013
Decision date	Apr 19, 2013
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medionics International, Inc.</b>
Location	Markham, Ontario, CA
Contact	MAHESH AGARWAL
510(k) history	4 submissions · 4 cleared · 1995-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130441/> 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 9, 2026