

**K090430 BACKSTOP AND BACKSTOP INJECTOR**Jun 2, 2009  
103 days to decisionK090430 · Product code: **ONJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k090430/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dissolvable Gel For Preventing Ureteral Stone Migration (ONJ)
Date received	Feb 19, 2009
Decision date	Jun 2, 2009
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pluromed, Inc.</b>
Location	Woburn, MA, US
Contact	JAMES WILKIE
510(k) history	4 submissions · 4 cleared · 2009-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090430/> 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 19, 2026