

K103349 BACKSTOP CATHETERJan 7, 2011
52 days to decisionK103349 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k103349/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Urological (KOD)
Date received	Nov 16, 2010
Decision date	Jan 7, 2011
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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