

K110491 BACKSTOP CATHETERMar 16, 2011
22 days to decisionK110491 · Product code: **KOD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k110491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urological (KOD)
Date received	Feb 22, 2011
Decision date	Mar 16, 2011
Days to decision	22 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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