

**K043241 LOFRIC HYDRO-KIT II SINGLE USE URINARY  
CATHETER**Dec 23, 2004  
30 days to decisionK043241 · Product code: **GBM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k043241/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Nov 23, 2004
Decision date	Dec 23, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Astra Tech, Inc.</b>
Location	Waltham, MA, US
Contact	BRUCE MANNING
510(k) history	28 submissions · 28 cleared · 1994-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043241/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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