

K050874 ASTRA TECH AB LOFRIC PRIMO SINGLE USE URINARY CATHETER

May 5, 2005
29 days to decision

K050874 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k050874/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Apr 6, 2005
Decision date	May 5, 2005
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k050874/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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