

**K012374 MODIFICATION TO: LOFRIC PLUS SINGLE USE
URINARY CATHETER**Aug 23, 2001
28 days to decisionK012374 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k012374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Jul 26, 2001
Decision date	Aug 23, 2001
Days to decision	28 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.netDevice record: <https://www.510kdatabase.net/k012374/> Data sourced from FDA 510(k) public records (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. - Generated June 13, 2026