FDA 510(k) Premarket Notification

K012374 MODIFICATION TO: LOFRIC PLUS SINGLE USE URINARY CATHETER

CLEARED

Aug 23, 2001
28 days to decision

K012374 · 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