

**K951479 CATHETERIZATION INSERTION PACK UROLOGICAL,
STERILE, DISPOSABLE**Jun 15, 1995
77 days to decisionK951479 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k951479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Mar 30, 1995
Decision date	Jun 15, 1995
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Trinity Laboratories, Inc.
Location	Raleigh, NC, US
Contact	B ASUMALLIK
510(k) history	44 submissions · 28 cleared · 1990-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951479/> 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 May 26, 2026