

K961442 UNIVERSAL DRAINAGE TRAYMay 9, 1996
24 days to decisionK961442 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k961442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Apr 15, 1996
Decision date	May 9, 1996
Days to decision	24 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Customed, Inc.
Location	Carolina Puerto Rico, US
Contact	FELIX B SANTOS
510(k) history	36 submissions · 26 cleared · 1990-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961442/> 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