

K942177 FOLEY CATHETERIZATION TRAYSep 8, 1994
127 days to decisionK942177 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k942177/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	May 4, 1994
Decision date	Sep 8, 1994
Days to decision	127 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

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