

K780735 URINARY CATHETER CARE SETJun 13, 1978
43 days to decisionK780735 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k780735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	May 1, 1978
Decision date	Jun 13, 1978
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Shield Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1977-1978

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