

K963993 RUSCH SIMPLASTIC FOLEY CATHETERIZATION SETDec 17, 1996
74 days to decisionK963993 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k963993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Oct 4, 1996
Decision date	Dec 17, 1996
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rusch, Inc.
Location	Jeffrey, NH, US
Contact	NEIL R ARMSTRONG
510(k) history	26 submissions · 24 cleared · 1993-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963993/> 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 25, 2026