FDA 510(k) Premarket Notification

K983010 SELF CATH SET/SAFETY CATH

CLEARED

Feb 12, 1999
168 days to decision

K983010 · Product code: **FCM** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k983010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Aug 28, 1998
Decision date	Feb 12, 1999
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rusch Intl.**
Location	Jeffrey, NH, US
Contact	KARENANN J BROZOWSKI
510(k) history	43 submissions · 43 cleared · 1995-2003