

**K983010 SELF CATH SET/SAFETY CATH**Feb 12, 1999  
168 days to decisionK983010 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k983010/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983010/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026