

**K070939 SELF-CATH CS CLOSED URINARY
CATHETERIZATION SYSTEM**Jun 1, 2007
58 days to decisionK070939 · Product code: **FCM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k070939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Apr 4, 2007
Decision date	Jun 1, 2007
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Manufacturing Us, LLC
Location	Minneapolis, MN, US
Contact	REBEKA STOLTMAN
510(k) history	4 submissions · 4 cleared · 2007-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070939/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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