

K223821 Self-Cath Closed SystemAug 2, 2023
224 days to decisionK223821 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Dec 21, 2022
Decision date	Aug 2, 2023
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast
Location	Plymouth, MN, US
Contact	Preeti Jain
Website	http://www.coloplast.com/
510(k) history	15 submissions · 14 cleared · 2018-2024

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