

K121383 PS X SERIES (BASIC COMPONENTS AND CATHETER), PD X SERIES (CATHETER WITH ALL COMPONENTS)Sep 5, 2012
120 days to decisionK121383 · Product code: **FJS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Peritoneal, Long-term Indwelling (FJS)
Date received	May 8, 2012
Decision date	Sep 5, 2012
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Components, Inc.
Location	Mchenry, IL, US
Contact	JEAN CALLOW
510(k) history	63 submissions · 55 cleared · 1980-2025

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