

K180070 SpeediCath Flex Coude ProFeb 2, 2018
24 days to decisionK180070 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Urethral (GBM)
Date received	Jan 9, 2018
Decision date	Feb 2, 2018
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180070/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026