

K121457 SPEEDICATH COMPACT SET (12 FR)Oct 2, 2012
139 days to decisionK121457 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k121457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	May 16, 2012
Decision date	Oct 2, 2012
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Coloplast Corp.
Location	Marietta, GA, US
Contact	BRIAN SCHMIDT
510(k) history	54 submissions · 47 cleared · 1985-2025

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