

K023254 SPEEDICATHJan 27, 2003
119 days to decisionK023254 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k023254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Sep 30, 2002
Decision date	Jan 27, 2003
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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