

K192904 SpeediCath Compact SetNov 2, 2020
384 days to decisionK192904 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k192904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Oct 15, 2019
Decision date	Nov 2, 2020
Days to decision	384 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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