

K172278 Firlit-Kluge Urethral Stent, Koyle Diaper Stent, Zaontz Urethral StentNov 22, 2017
117 days to decisionK172278 · Product code: **GBM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k172278/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Jul 28, 2017
Decision date	Nov 22, 2017
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	Samuel Engelman
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172278/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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