

K182709 One-Step Suprapubic IntroducerDec 26, 2018
90 days to decisionK182709 · Product code: **KOB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Sep 27, 2018
Decision date	Dec 26, 2018
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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