

**K182066 O'Brien Suprapubic Introducer Set, Cook SP
Tube Introducer Set**

Oct 30, 2018
90 days to decision

K182066 · Product code: **KOB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k182066/>

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Catheter, Suprapubic (and Accessories) (KOB)
Date received	Aug 1, 2018
Decision date	Oct 30, 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182066/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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