

K191015 Soft-Pass Embryo Mock Transfer Catheter Sets (Soft-Pass Embryo Mock Transfer Catheter Set and Soft-Pass Embryo Mock Transfer Catheter Set with Echogenic Tip)May 17, 2019
30 days to decisionK191015 · Product code: **MQF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Apr 17, 2019
Decision date	May 17, 2019
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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