

K180302 Guardia™ Access Malleable Obturator, Guardia™ Obturator, Soft-Pass™ Obturator, Soft-Trans Malleable Obturator, Guardia™ ETS Embryo-Tested Syringe, Flushing CatheterOct 24, 2018
264 days to decisionK180302 · Product code: **MQF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k180302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Feb 2, 2018
Decision date	Oct 24, 2018
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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