

K172051 Guardia™ Access Nano and Soft-Trans Embryo Transfer Catheter Sets, Soft-Trans Embryo Transfer Catheter, Soft-Trans Guide CatheterJan 10, 2018
188 days to decisionK172051 · Product code: **MQF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k172051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Jul 6, 2017
Decision date	Jan 10, 2018
Days to decision	188 days
Third-party review	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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