

**K173686 Guardia Access Embryo Transfer Catheter Sets and Sydney IVF® Transfer Catheter**

Apr 11, 2018  
131 days to decision

K173686 · Product code: **MQF** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k173686/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Dec 1, 2017
Decision date	Apr 11, 2018
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k173686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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