

K171625 Single Lumen Ovum Aspiration NeedlesJan 12, 2018
224 days to decisionK171625 · Product code: **MQE** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k171625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Jun 2, 2017
Decision date	Jan 12, 2018
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Willian A. Cook Australia Pty, Ltd.
Location	Eight Mile Plains, AU
Contact	Gordana Pozvek
510(k) history	2 submissions · 2 cleared · 2016-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171625/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 31, 2026