

**K152904 SYDNEY IVF EMBRYO BIOPSY MEDIUM**Dec 3, 2015  
63 days to decisionK152904 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k152904/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Media, Reproductive (MQL)
Date received	Oct 1, 2015
Decision date	Dec 3, 2015
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>William A. Cook Australia Pty. , Ltd.</b>
Location	Eight Mile Plains, Qld, AU
Contact	GORDANA POZVEK
510(k) history	14 submissions · 14 cleared · 2009-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152904/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026