

K152782 SYDNEY IVF SPERM MEDIUM, SYDNEY IVF SPERM GRADIENT KIT, SYDNEY IVF SPERMIENT

Dec 21, 2015
87 days to decision

K152782 · Product code: **MQL** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k152782/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Media, Reproductive (MQL)
Date received	Sep 25, 2015
Decision date	Dec 21, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152782/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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