

K153478 Sydney IVF Gamete BufferAug 15, 2016
257 days to decisionK153478 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k153478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Dec 2, 2015
Decision date	Aug 15, 2016
Days to decision	257 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

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