

K082363 COOK SYDNEY IVF BLASTOCYST VITRIFICATION (K-SIBV-5000), WARMING (K-SIBW-5000) KITSApr 29, 2009
254 days to decisionK082363 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k082363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Aug 18, 2008
Decision date	Apr 29, 2009
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082363/> 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 30, 2026