

K021358 EMBRYO BIOPSY MEDIUMJul 5, 2002
67 days to decisionK021358 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k021358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Apr 29, 2002
Decision date	Jul 5, 2002
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Irvine Scientific Sales Co., Inc.
Location	Santa Ana, CA, US
Contact	WENDELL LEE
510(k) history	40 submissions · 40 cleared · 1997-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021358/> 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 June 1, 2026