

**K033462 EARLY CLEAVAGE MEDIUM (ECM)**Jan 15, 2004  
76 days to decisionK033462 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k033462/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 31, 2003
Decision date	Jan 15, 2004
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033462/> 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 June 1, 2026