

**K983589 P-1 (PREIMPLANTATION STAGE ONE) MEDIUM**Feb 18, 1999  
128 days to decisionK983589 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k983589/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	Oct 13, 1998
Decision date	Feb 18, 1999
Days to decision	128 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	ROBERTA L JOHNSON
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/k983589/> 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