

**K971809 ISOLATE**Jul 3, 1997  
49 days to decisionK971809 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k971809/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Media, Reproductive (MQL)
Date received	May 15, 1997
Decision date	Jul 3, 1997
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971809/> 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